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Stephan Reichmuth Winterthur Strat Sourcing REICHMUS	27.03.2020 / 14:11 CET	Genehmigung - Autor Autor
Tobias Zatti Supplier Quality Assurance ZATTIT	30.03.2020 / 08:12 CET	Genehmigung - Prozesseigner Prozesseigner
Gustavo Romero Sourcing ROMEROG	30.03.2020 / 09:13 CET	Genehmigung - Subject Matter Experts Subject Matter Expert
Larissa Birnbaum Regulatory Compliance BIRNBAUL	30.03.2020 / 11:11 CET	Genehmigung - Regulatory Compliance Regulatory Compliance

1. Purpose

The purpose of this Supplier Quality Guidebook is to communicate information on quality expectations to Zimmer Biomet Winterthur suppliers that have quality impact on Zimmer Biomet Winterthur's Quality Management System and/or product quality.

2. Process Owner

Supplier Quality Manager

3. Scope

This document applies to Zimmer Biomet Winterthur.

4. Applicable Documents

Listed below are the documents that are applicable for this document:

- N/A

Table of Content

5. Abbreviations and Definitions

Following abbreviations and definitions pertain to this document:

Abbreviation / Term	Definition
CNC	Computerized Numerical Control
CpK	long term capability study
FDA	Food and Drug Administration
NDT	Non-destructive Testing
Ppk	Process Performance Capability Index
RoHS	Restriction of Hazardous Substances

6. General Requirements

6.1 Zimmer Biomet Corporation

ZIMMER

From the very beginning our goal at Zimmer Biomet has been to create new possibilities for healthcare professionals and their patients.

The story begins in Warsaw, Indiana, in 1926. Justin O. (J.O.) Zimmer had been working for a company that made wooden splints for 20 years. When aluminum became widely available, J.O. suggested to the company's ownership that it would be an excellent material for manufacturing splints. His idea was rejected.

In response, J.O. decided to start a splint manufacturing business of his own. He found two investors, William Felkner and William Rogers, and hired J.J. Ettinger to act as factory manager and Dona Belle Harmon Cox as secretary and bookkeeper. In early 1927, working out of the Zimmer house at Winona Avenue and Indiana Street, J.O., Ettinger, and Dr. Lytle (a physician and sales colleague of Mr. Zimmer) worked to develop a set of 50 different aluminum splints and other orthopaedic equipment.

When J.O. presented these products at the American Medical Association's annual meeting, he completely changed the orthopaedic industry. Doctors immediately recognized the superiority of strong, lightweight aluminum for splinting their patients. With this success, Zimmer quickly gained a leading position in the market.

For the next several decades, Zimmer innovations provided surgeons with many new options for treating their patients. The company thrived and expanded, and acquired numerous smaller companies known for innovation, adding their capabilities to Zimmer's growing portfolio. The company pioneered new implants and new materials, surgical devices, and bone cements. In 1972, Zimmer was itself acquired by a much larger entity, Bristol-Myers.

BIOMET

In 1977, Dane A. Miller, Ph.D., Niles L. Noblitt, Jerry L. Ferguson and M. Ray Harroff, founded Biomet. Like Justin Zimmer, Biomet's founders chose Warsaw, Indiana as its headquarters. Dane Miller, the company's first and longest-serving CEO, and Jerry Ferguson began their orthopaedic careers at Zimmer.

Biomet rapidly established itself as a champion of biomaterials and design advances that would become industry standards, including direct compression molded polyethylene, titanium alloy in cementless reconstructive products, and PPS® porous plasma spray coating. In 1978, Dane's maternal grandmother received Biomet's first hip implant, further demonstrating the founders' firm belief in their new company and its products. Biomet went public in 1982, and by the end of its first decade, Biomet had gained state and national recognition for its unique corporate philosophy and culture, which focused on customer responsiveness, teamwork and innovation.

Throughout the 1980s and 1990s and into the new millennium, Zimmer and Biomet continued to innovate and expand. Along the way, these two companies never lost sight of their mission: to remain totally committed to the healthcare professionals they served, and to apply their proven research and development expertise to the task of improving the lives of patients.

In 2014 the story came full-circle. Zimmer – now an independent, publicly-traded company, having been spun out of Bristol-Myers Squibb in 2001, and Biomet, having been purchased by a private equity consortium in 2007 – realized that the companies could accomplish more together than would be possible as separate companies. In April 2014, Zimmer President and CEO David Dvorak announced plans to create a new company by combining the best of Zimmer and Biomet. It would be, he said, “a major win for all of our healthcare stakeholders. We are combining two companies with complementary portfolios of solutions and proven innovation capabilities, supported by leading global sales teams and a highly skilled manufacturing force. Through this merger, we will underscore our commitment to support healthcare providers and their patients with a broader range of personalized solutions, superior technology and new innovations that enhance clinical outcomes and improve quality of life.”

ZIMMER BIOMET BECAME A REALITY IN JUNE 2015

Two great companies have come together behind one defining promise: To discover and achieve new possibilities for patients, healthcare professionals and for our own Team Members.

The Zimmer Biomet, Inc. corporate headquarters are located at:

345 MAIN STREET, WARSAW, IN 46581, USA

6.2 Zimmer Biomet Mission / Guiding Principles / Values / Quality Policy

6.2.1 Our Mission

Alleviate pain and improve the quality of life for people around the world.

6.2.2 Guiding Principles / Values

- Respect the contributions and perspectives of all Team Members
- Commit to the highest standards of patient safety, quality, and integrity
- Focus our resources in areas where we will make a difference
- Ensure the company’s return is equivalent to the value we provide our customers and patients
- Give back to our communities and people in need

6.2.3 Corporate Quality Policy

6.2.4 Key Global Zimmer Biomet Quality System Requirements for Supplier Management

Quality Management Responsibility	Quality Management Controls	Supplier Approval Process
Supplier Production Process ApprovalTeam Process	Production & Process Controls	Change Controls
Control of Non-conforming Products	Inspection / Measurement / Testing Equipment	Internal & External Audit Assessments
Corrective & Preventive Actions	Records	Supplier Performance

The purpose of this Supplier Quality Guidebook is to clearly communicate, as One Zimmer Biomet, information on quality expectations to suppliers, including raw material, component, Original Equipment Manufacturers (OEM), contract manufacturers of semi-finished and finished instrument and implantable devices, packaging, and service suppliers associated with product. The external supply chain plays an important role as a business partner with Zimmer Biomet and it is imperative that suppliers understand the importance of the key quality system requirements.

The quality requirements apply to the development and manufacture of all products/services supplied to Zimmer Biomet. These requirements are established through Contracts and/or Purchased Orders (PO) issued by Zimmer Biomet with appropriate quality and product specifications. Since suppliers are critical to Zimmer Biomet's success in delivering high quality product to our customers at the right time, it is important for us to set expectations, identify gaps, and track progress of gap resolution. Zimmer Biomet considers establishing preferential long-term relationships with those suppliers who are committed to achieving, and sustaining, these requirements.

Quality Requirements may take the form of a stand-alone Supplier Quality Agreement (SQA) or a long term supply agreement contract with the SQA as an exhibit. Also, Quality requirement encompass the requirements set forth in this Supplier Quality Guidebook as well as in other documents such as engineering specifications.

The requirements within this Supplier Quality Guidebook are provided as a supplement to the terms or conditions of the Contract or PO, engineering drawings, or specifications.

Zimmer Biomet understands that our business sectors are different in nature and may have unique supplier quality requirements. However, the processes and tools described in this Supplier Quality Guidebook represent the core One Zimmer Biomet expectations and requirements. Any differences suppliers may encounter across the Zimmer Biomet organization will generally be minimal and driven by customer, product, and/or market specific requirements.

6.2.5 Supplier Diversity and Code of Conduct

Diversity

A diverse supply chain strengthens our ability to carry out our mission and improve the communities that we live and work. Zimmer Biomet has diversity reporting obligations to the US Federal Government for spending in the USA and Puerto Rico. It is important to that our records are up-to-date, so any diversity status changes will be reported to Zimmer Biomet through your Sourcing and/or Supplier Quality contact. Below are the 6 diverse supplier categories Zimmer Biomet reports to the government annually.

1. Historically Underutilized Business Zone Small Business (HUBZone)
2. Service-Disabled Veteran-Owned Small Business (SDVOSB)
3. Small Business (SB)
4. Small Disadvantaged Business (SDB)
5. Veteran-Owned Small Business (VOSB)
6. Women-Owned Small Business (WOSB)

Zimmer Biomet prefers nationwide and US Government certifications as evidence of confirmed diversity status. Suppliers can self-certify for the small, women, and veteran categories. HUBZone suppliers require US Government certification evidence. Moreover, as our customers continue to request Tier II diversity reports, Zimmer Biomet will request supplier diversity spend data to fulfill the various diversity reporting obligations that occur throughout the fiscal year.

Code of Conduct

Zimmer Biomet strives to achieve and maintain the highest possible standards of corporate integrity and ethical behavior. Zimmer Biomet expects that its Suppliers will conduct their business not only in a lawful manner but also in compliance with the same high standards of integrity and ethics. In order to establish guidelines for such standards, Zimmer Biomet has established this Code of Supplier Conduct. This Code is not meant to be all-inclusive or exhaustive. The Code sets forth and highlights important legal, ethical, behavioral and other requirements for parties who wish to be a Zimmer Biomet Supplier. Zimmer Biomet Suppliers are further expected to take reasonable and necessary steps to help ensure that their sub-contractors and sub-suppliers conduct business in compliance with this Code of Supplier Conduct. Zimmer Biomet reserves the right to amend, modify and add to this Code of Supplier Conduct from time to time as Zimmer Biomet, in its sole discretion, believes is appropriate.

Compliance with Applicable Laws, Regulations, and Industry Best Practices: At a minimum, Suppliers must conduct business in accordance with all applicable country, state, and local laws and regulations covering the jurisdictions in which they operate including, without limitation, laws relating to employment, human rights, the environment, health and safety, and trade. Supplier is to comply with the commercial best practices of Supplier's industry. Zimmer Biomet reserves the right to decline to deal with Suppliers who do not comply with the law. For further guidance of the Zimmer Biomet Code of Conduct please go to the supplier section at www.zimmerbiomet.com.

6.2.6 Zimmer Biomet Supplier Focus / Expectations

Quality

Zimmer Biomet requires world-class quality for all purchased materials, products, and services that are supplied to our patient and physician customers. Our suppliers directly share in the responsibility to ensure that the highest degree of care is taken to meet or exceed all specified safety, compliance, quality, and reliability requirements.

Supplier Expectations

It is Zimmer Biomet's expectations that:

- Suppliers provide data to demonstrate compliance to applicable external regulations and standards.
- Materials, components, assemblies, services and finished medical devices supplied to Zimmer Biomet meet or exceed all quality and product specification requirements.
- After production equivalency has been established, all changes related to Zimmer Biomet products as defined in the Device Master Record (DMR), including subcomponents, materials, and processes used on these products, will be submitted to Zimmer Biomet for approval prior to implementation.
- Suppliers have a compliant Quality System that meets Zimmer Biomet Supplier Assessment Requirements.
- Suppliers review and sign a Supplier Quality Agreement (SQA) when required.
- If applicable, suppliers of semi-finished and finished devices maintain a manufacturing environment with appropriate temperature, humidity or other environmental controls, as determined by the raw material, component, Original Equipment Manufacturer (OEM), or service suppliers associated with product.
- Supplier has a master validation plan established to monitor and control of process validations.
- Supplier maintains a Device History Record (DHR) for the manufacturing and quality documentation of each lot/batch produced.
- Suppliers support regulatory audits and unannounced audits by notified bodies.

- Supplier support for projects, continuous improvements, and necessary registration for Zimmer product: e.g. FDA device registration through the FURLS process per part 21 CFR part 807 and other Third Party Registration.
- Delivery performance to Zimmer Biomet's Purchasing Orders is on time every time and in full.
- Delivering to the Requested Delivery Date in order to maintain a 95% On-Time-In-Full (OTIF) Delivery Metric.
- Supplier lead-time for manufacturing are communicated real-time to Zimmer Biomet if they change. This communication needs to go to the Buyer of the product.
- Suppliers need to communicate capacity constraints as soon as they are identified; this communication goes to the Buyer.

Technology

Zimmer Biomet seeks to partner with suppliers with demonstrated technology leadership and a commitment to investing in continued technology development. Zimmer Biomet also expects all suppliers to:

- Implement formal, management-sponsored continuous improvement initiatives. Examples include Six Sigma, Lean, or Total Quality Management initiatives.
- Implement Statistical Process Controls (SPC) for all critical input and output process variables to enable sampling and remove 100% inspection requirements.
- Achieve process capabilities for all critical input and output process variables, to enable sampling and removed 100% inspection.
- Strategic suppliers with long term agreements are also expected to invest and keep current with the latest technologies and capabilities.

Measurements

Zimmer Biomet seeks to partner with suppliers with demonstrated technology leadership and a commitment to investing in continued technology development. Zimmer Biomet also expects all suppliers to:

- Implement formal, management-sponsored continuous improvement initiatives. Examples include Six Sigma, Lean, or Total Quality Management initiatives.
- Implement Statistical Process Controls (SPC) for all critical input and output process variables to enable sampling and remove 100% inspection requirements.
- Achieve process capabilities for all critical input and output process variables, to enable sampling and removed 100% inspection.
- Strategic suppliers with long term agreements are also expected to invest and keep current with the latest technologies and capabilities

Trade Compliance

As a Global Organization, Trade Compliance is a key part in moving product, equipment, and other business requirements across many International Country borders. Zimmer Biomet expectations are that the supplier chain complies, and assist Zimmer Biomet with all governmental requirements for Trade Compliance. Trade Compliance is about compliance with international border crossing related laws, rules, and regulations, as well as company policies and procedures. Key elements of Trade Compliance are mentioned in the following table:

Customer Compliance	Export Controls, Sanctions and Embargoes
• Customs clearances • Country specific import/export requirements • Country of Origin • Commodity Codes Harmonized System (HS) • Customs Valuation • Customs Brokers	• Export control classification, Dual-Use goods (like assets, Information Technology (IT)) • Anti-boycott • Licenses • Sanctions
Controls	
• Approval requirements • Transaction controls: Manual and Automated Global Trade Services (GTS) • Monitoring • Trade Compliance audits	

6.2.7 Supplier Lifecycle Management Element Structure

6.2.7.1 Supplier Lifecycle Management Structure

Zimmer Biomet continually enhances its position as a world-class medical device provider. To maintain this leadership, the mission of the Zimmer Biomet Global Supply Chain organization is to establish world-class practices for all purchased materials, products, and services. The organizations global supplier quality management requirements are governed within the Supplier Lifecycle Management structure. Zimmer Biomet is committed to developing and fostering supplier relationships that will deliver industry-leading safety, quality, reliability, and value to our patient and physician customers. The Supplier Lifecycle Management structure is based on the Global Harmonization Task Force supplier quality management process flow.

In pursuit of this mission, we have developed a comprehensive supplier management program, as illustrated in the Supplier Lifecycle Management Structure. The supplier control process ensures that the quality of the supplied materials, products, or services meets Zimmer Biomet specified purchase requirements. Zimmer Biomet uses a systematic approach to manage in the processes of the Supplier Lifecycle Management Structure.

Zimmer Biomet will select and partner with suppliers who are committed to working together toward a common goal and who share our commitment to the best practices outlined in this Supplier Quality Guidebook. These best practices and supplier's performances are continuously monitored with business reviews, supplier scorecards, key performance indicators (KPIs) metrics, and assessments.

Initial evaluation requirements to be a supply chain partner with Zimmer Biomet.

Zimmer Biomet requires all suppliers of raw materials, components, finished devices, special processes, software, catalogue items, and services as related to medical devices, as well as strategic alliance partners used by Zimmer Biomet and its subsidiaries, to be approved prior to the issuance of contracts based on the evaluation of the supplier's quality system. All suppliers will be approved by Zimmer Biomet, regardless of approvals by customers or other entities.

6.2.7.2 Planning and Search of Potential Suppliers

Planning

Zimmer Biomet offers a broad portfolio of market-leading products and is committed to patients, physicians and healthcare providers. Key to this effort is a focused and effective new product development process. This process also includes the transfer of legacy product throughout the global network of supply chain manufacturing sites throughout the world.

Zimmer Biomet determines the quality and product specification requirements for the product/service the supplier will meet per the DMR. Quality and regulatory requirements specified by Zimmer Biomet, including requirements for delivery and post-delivery of product.

Before committing to supply any product or service to Zimmer Biomet, the supplier will hold a contract review for the Zimmer Biomet requirements related to the product. This is essential to ensure that the product or service requirements are defined, order requirements are understood, and the supplier has the ability to meet the defined requirements per the acceptance of the Zimmer Biomet Purchase Order.

Evaluation

The level of evaluation within the selection process is based upon the potential risk of the sourcing decision, as determined by a number of factors, including but not limited to supplier history and the requirements of the particular material, component, assembly, service or finished medical device to be purchased. Strategic suppliers will be considered first for new business.

Supplier Selection

The process of selecting suppliers for materials, components, finished medical device products or services is an integral part of Zimmer Biomet's commitment to delivering world-class medical devices to our customers.

Our principal interest is to ensure that the selected suppliers are aligned with Zimmer Biomet quality, technology and business goals. The supplier selection process is also used to identify potential risks in the supply chain, so that risks can be mitigated or eliminated prior to production.

When selecting a supplier, Zimmer Biomet will evaluate both existing and new suppliers. The key areas evaluated are:

Quality: Capability to repeatedly produce product which meets or exceeds the technical and quality requirements of Zimmer Biomet.

Technology: Technical capability and commitment to advancing process technologies in support of Zimmer Biomet strategic direction.

Service: Capability to meet Zimmer Biomet production, delivery and service requirements with a demonstrated high level of support and responsiveness.

Value: Competitive pricing, cost reduction capabilities and active participation in inventory management initiatives.

Diversity: Diverse supplier types that are capable of meeting Zimmer Biomet quality, technical, service, and value requirements.

6.2.7.3 Supplier Evaluation and Disposition Process

The Supplier Initial Assessment

Zimmer Biomet may request the supplier to provide a copy of its quality management system certificate and/or complete a self-assessment of its business and quality management system and capabilities (e.g. quality, delivery, technology, cost, and continuous improvement objectives).

Through the supplier qualification process, Zimmer Biomet may request a copy of the supplier's Quality Manual document and supporting procedures (and may include internal audit reports, etc.) to determine if the supplier's quality management system meets Zimmer Biomet requirements.

Through the supplier qualification process, Zimmer Biomet may request key process procedures or work instructions to determine if those processes are governed appropriately.

Business and Manufacturing Operations: To determine whether the Supplier has the financial resources, production capacity, and other business resources needed to fulfil Zimmer Biomet volume production needs and assure continuity of supply.

Continuous Improvement Initiative: To determine if the supplier's culture, methods and skills are present to actively pursue continuous improvement

On-site Assessment

Due to product/process complexity, criticality or patient/user risk, Zimmer Biomet may elect to conduct on-site assessments of a supplier's product or process capabilities per a define project plan. These assessments may include, but not limited to the following:

Quality Management System (QMS): Product or process capability assessments, to determine whether the supplier's quality management system meets the applicable regulations and standards, and is functioning effectively.

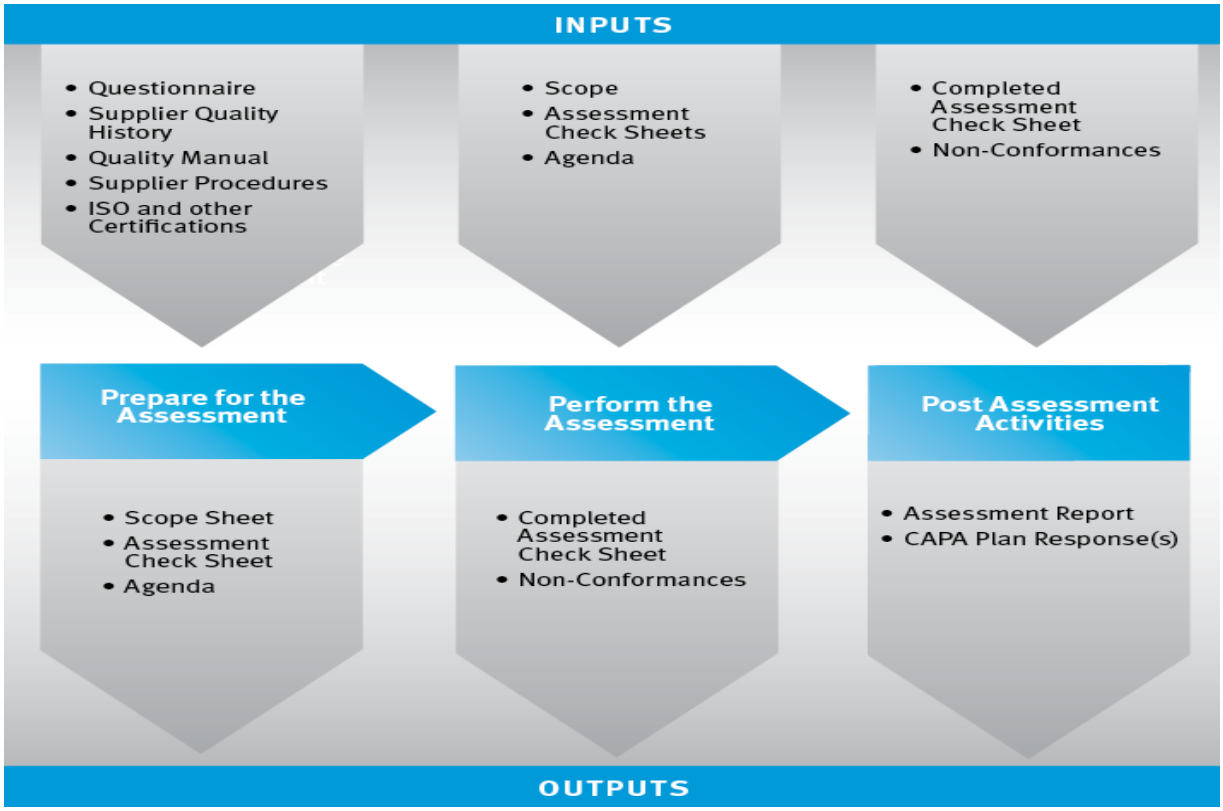
Technology Assessment: To determine whether the supplier has the required technical resources, including but not limited to production and inspection equipment, facilities, engineering resources.

Sub-Tier Supplier Control: To evaluate the effectiveness of the supplier's sub-tier management processes and ensure that products or services procured, and delivered; from sub-tier sources meet established process and quality expectations.

Supplier Periodic assessments: There will be an ongoing review of supplier performance to determine frequency and type of subsequent audit requirements. Zimmer Biomet may audit a supplier's product or process capabilities when:

- Based on supplier risk classification classified as defined by Zimmer Biomet
- There is expansion of supplier scope, including risk level of product.
- Periodic onsite audits of critical and key suppliers are called for.
- There is an insufficient response in one or more elements of the Supplier Assessment Survey or a Supplier Corrective Action Report (SCAR).
- Significant process changes occur, such as: facility changes, workforce turnovers, etc.
- There is a significant drop or downward trend in the Supplier's Quality and or Delivery rating (Scorecard).
- Existing product issues affect delivery or critically timed product launches.
- A significant quality issue occurs and additional review is warranted to confirm corrective actions.
- Post assessment activities supplier CAPA plan will be tracked through the Zimmer Biomet Supplier Corrective Action Report (SCAR) process.

SUPPLIER ASSESSMENT INPUTS AND OUTPUTS



Implantable Raw Material

Implantable raw material suppliers and distributors will be assessed, audited, approved, and controlled pursuant to the Zimmer Biomet implantable raw material supplier guidance procedure requirements.

The scope of the raw material guidance procedure includes:

- Melt facilities, regardless of common quality systems require a QMS and process check list audit
- Mill\Converters\Extruders regardless of common quality systems require a QMS and process check list audit. The exception is where a primary Mill\Conversion supplier contracts with an intermediary source for processing of medical grade alloys.
- If the primary Mill\Converter/Extruders has adequate supplier controls and has demonstrated compliance to applicable testing\verification and traceability requirements prior to releasing the processed material for distribution, the contracted intermediary is not required to be audited by Zimmer Biomet.
- Zimmer Biomet reserves the right to review supplier validations documentation, along with sub-tier supplier validation documentation. The supplier validation requirements will be governed under the Zimmer Biomet guidance Supplier validation review and disposition procedure requirements.

Distributors of implantable raw materials require an initial QMS audit. The exception is where an implantable raw material manufacturer has a common quality system that each distribution site and its physical address are identified within the scope of the manufacturer primary quality certificate.

Traceability will be established by Heat (Ingot) and final Lot (each manufacturing stage). Lot number may be sale order numbers, purchase order numbers or any unique identifier utilized by the manufacture.

Suppliers that provide implantable finished or unfinished devices will purchase their implantable raw material from a Zimmer Biomet applicable approved implantable raw material approved supplier list.

- Zimmer Biomet will provide the supplier access to applicable implantable raw material approved supplier list.
- The supplier will designate which implantable raw material supplier they used to manufacture the Zimmer Biomet product on each shipment C of C / C of A.
- Once a supplier has chosen the implantable raw material supplier for the Zimmer Biomet product, they cannot change suppliers for the product raw material until a change request is approved by Zimmer Biomet Change Notification process.
- If a supplier determines they want to change to another implantable raw material supplier, the Zimmer Biomet site will follow the current part approval requirements; it is recommended that the Zimmer Biomet assess the output of the supplier's product and processing differences based on using a different supplier prior to the change of material.
- The supplier will provide the implantable raw material C of C / C of A that indicates the material was tested to the applicable Zimmer Biomet material specifications or applicable material standard such as ASTM, AMS or ISO.

Supplier Validations

Zimmer Biomet defines the processes for reviewing and disposition of supplier process validations, including but not limited to, manufacturing, packaging and sterilization processes which require validation.

The focus to determine when process validations are required is based on the processes that cannot be fully verified or the supplier is attempting to reduce 100% inspection to sample planning for products define critical to quality (CTQ) characteristics.

When a supplier validation has gone through the review and disposition requirements, and the same revision of the validation is being considered as part of a new production transfer plan, it is the supplier responsibility to provide an “adoption” report that gives rationale that the product being transferred under the new project is not a “new worst case” part for the current validation.

Suppliers including sub-tier suppliers which do not have adequate process validation performed for processes that require validation are required to remediate such process validation and contain any impacted product.

Supplier validation requirements for a project are defined within the supplier selection process, along within the supplier production part approval process.

6.2.7.4 Finalization of Controls

Critical to Quality Specification Characteristics

CTQ’s are the key measureable specification characteristics of a product whose performance standards or specification limits will be met in order to satisfy the customer. CTQ’s are further defined as those design outputs that are essential for the proper functioning of a device. Zimmer Biomet Development Engineering is responsible to assess and assign the criticality for each specific feature as part of defining the specification characteristics feature specification risk level. The criticality is assessed by considering what Hazard(s) and Harm(s) could result if the function of that feature were minimized or lost.

Zimmer Biomet has defined requirements for the evaluation of each specification characteristic against the risk of failure of each characteristic based on the products Design Failure Mode Effects Analysis (DFMEA). Each specification characteristic is given a define risk number for each DFMEA line item that is associated the severity of failure that would affect the customer (i.e. patient risk). The higher risk numbers will be associated to the characteristics specification defined as CTQ.

During the product/service production transfer requirements for New Product Integration (NPI) of a New Product Development (NPD) project, or legacy product that has previously completed the NPD phase/gate commercialization requirements, Zimmer Biomet Quality Engineering will provide the defined characteristics specification CTQ’s to the supplier that will be produce the product/service being transferred.

CTQ’s will be defined by Zimmer Biomet and will be reviewed between the Supplier and Zimmer Biomet Supplier Quality Engineering as part of the Production Part Approval Process quality and process requirements. However, compliance to all the print and quality/product specifications is expected. As part of the Production Part Approval Process requirements, the supplier will be responsible to focus their process and quality requirements on the Zimmer Biomet provided characteristics specification CTQ’s.

Supplier Production Process Approval (SPPA)

The SPPA consists of stages of project planning/implementation requirements between Zimmer Biomet and supplier to establish the appropriate controls for production processes. The process is implemented in phases with specific requirements that will be met, and approved, before moving into the next phase.

The production process requirements may include supplier validations, contact materials, non-destructive testing, process flow, special process validations, Process Failure Mode Effects Analysis (PFMEA) or another proven risk assessment approved by Zimmer Biomet, process control plans, inspection plans, process capability study with control charts, material testing certifications, certification of analysis/conformance, measurement systems analysis, and test method validations.

The supplier will demonstrate conformity to those designated characteristics for product process requirements and product specifications designated by Zimmer Biomet through means of documentation and appropriate control methods. In addition to any designated specification characteristics for product process requirements and product specifications identified by Zimmer Biomet, the Supplier will also review, identify, document, and control other product and process characteristics that are key to achieving quality.

Key Production Control Elements of SPPA Process

Process Flow Diagram: The Supplier will create a flow diagram of the proposed and/or current process. This diagram will clearly describe the production process sequence that is necessary to meet Zimmer Biomet needs, requirements, and expectations.

Process Failure Mode Effects Analysis Diagram: The Supplier will create a PFMEA diagram identifying potential process failure modes and identifying the effects of those failures. Requirements driven to the supplier by Zimmer Biomet for the PFMEA diagram will be based on deliverables established by the project, and will be compliant to Zimmer Biomet specified conditions. A single process PFMEA diagram may be applied to a process for manufacturing a family of similar parts or materials, if reviewed, and approved, for commonality by Zimmer Biomet.

NOTE: If a PFMEA diagram is not used, an alternate risk method can be used that is internationally recognized, and approved by Zimmer Biomet.

Control Plan: The supplier will have a Control Plan that defines all methods used for process monitoring and control of special product/process characteristics. The control plan will be updated accordingly during the development of the process, and will be finalized once the process goes into full production mode. A single control plan may apply to a group or family of products that are produced by the same process at the same source.

Sampling Inspection: Where the supplier has statistical rationale, has defined process controls in place, and can demonstrate ongoing process monitoring capability, sampling plans may be deployed. The supplier is still responsible for 100% of quality for all items delivered to Zimmer Biomet.

Special processes will be 100% inspected until process validation is completed. Sampling is only allowed for CTQs after a process validation has been completed. If a validation is not performed or statistical capability requirements cannot be met for CTQ's, 100% inspection is required.

When the Supplier elects to use statistical methods for the acceptance of products or processes, such methods will utilize a statistically valid rationale. The criteria for lot acceptance is zero (i.e. C=0). The supplier control plan will reflect the sample plan requirements.

NOTE: In cased where the only method of inspection would be destructive testing, validation is required as 100% inspection would destroy all produced product.

Measurement Systems Analysis: The supplier will develop or obtain gauges and standards to control their processes and to determine product conformance to specifications. Variable gauges and measurements are preferred. Alternative methods, gauges, or standards may be used at Zimmer Biomet to verify the supplier's inspection results. Zimmer Biomet may request the supplier to participate in a correlation study to compare supplier measurement results against results obtained by Zimmer Biomet gauges and methods.

The supplier will perform Measurement Systems Analysis (MSA) studies for all new/ modified gauges, measurement or test equipment. MSA study focus will be toward Critical to Quality (CTQ). At a minimum a Gauge Repeatability & Reproducibility (GR&R) Study is to be conducted. Zimmer Biomet Supplier Quality may require that other tests such as bias, linearity, and/or stability be conducted as appropriate. A reference that can be used for MSA studies is the Automotive Industry Action Group (AIAG) MSA requirements document. Web information can be found going to www.aiag.org.

The guidelines for acceptance of gauge GR&R as a percentage:

- Less Than 10% error – the measurement system is acceptable.
- 10%-30% – may be acceptable based upon importance of application, cost of gauge, cost of repairs, etc. of which will be reviewed by Zimmer Biomet Supplier Quality Engineering.
- Greater Than 30% error – needs improvement unless approved by Zimmer Biomet Supplier Quality Engineering.

Process Capability & Process Capability Performance Study's (CpK, PpK): Suppliers will be capable and willing to monitor real-time process data, implement Statistical Process Control (SPC) and provide capability studies on CTQs as requested by Zimmer Biomet.

All CTQ features, as agreed to, will be controlled with SPC and variable and/or fixed gaging as applicable.

If the supplier is not able to achieve or monitor process performance capability, as specified per Zimmer Biomet project requirements, the supplier must monitor through 100% inspection of CTQ's per established control plan.

The statistical distribution should be determined prior to estimating capability. If the process is not in statistical control, all assignable causes will first be identified and corrected.

Process Performance Validation Capability Index (PpK) is a comparison of the inherent variability of a process output to specification limits under statistically stable conditions. Most methods for estimating capability require that the characteristic being evaluated is approximately normally distributed, and in statistical control.

When the process is not normally distributed using standard statistical techniques, special distribution models are available for calculating capability. When such models are used, this will be communicated to Zimmer Biomet Supplier Quality for consensus.

Definitions and calculations for CpK & PpK indices are found in AIAG, PPAP and SPC Manuals. Unless otherwise approved by Zimmer Biomet, the Supplier will use the following as acceptance criteria for evaluating initial process study results of special characteristics for processes that appear stable:

Results Interpretation for a sample size of ≥ 30:

- Index ≥ 1.33 the process currently meets acceptance criteria
- Index < 1.33 the process may not be acceptable

Process Validations: Process validation is establishing by objective evidence that a process consistently produces a result or product meeting its predetermined requirements. Per the 21CFR 820.75 Process Validation, where the results of a process cannot be fully verified by subsequent inspection and test process validation can be used to reduce inspection sampling levels, the process will be validated with a high degree of assurance and approved according to established procedures for process capabilities. If a validation is not performed or statistical capability requirements cannot be met for CTQ's, 100% inspection is required.

NOTE: In cases where the only method of inspection would be destructive testing, validation is required as 100% inspection would destroy all produced product.

Validation of a process entails demonstrating that, when a process is operated within specified limits, it will consistently produce product complying with predetermined (design and development) requirements. The supplier will be responsible to monitor and control process validations per their master validation plans.

The Three key elements of Process Validation (According to requirements found within the GHTF Subgroup 3 document)

Installation Qualification (IQ): IQ establishes by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer's approved specification and that the recommendations of the supplier of the equipment are suitably considered. Important IQ considerations are:

- Equipment design features (e.g. materials of construction, cleanability, etc.)
- Installation conditions (wiring, utilities, functionality, etc.)
- Calibration, preventative maintenance, cleaning schedules
- Safety features
- Supplier documentation, prints, drawings and manuals
- Software documentation
- Spare parts list
- Environmental conditions (such as clean room requirements, temperature, humidity)

Operational Qualification (OQ): In this phase the process parameters will be challenged to assure that they will result in a product that meets all predetermined requirements under all anticipated conditions of manufacturing (i.e., worst case testing).

During routine production and process control, it is desirable to measure process parameters and/or product characteristics to allow for the adjustment of the manufacturing process at various actions to level(s) while still maintaining a state of control. These action levels will be evaluated, established and documented during process validation to determine the robustness of the process and ability to avoid approaching worst case conditions.

Statistically valid techniques, such as screening experiments to establish key process parameters and statistically designed experiments to optimize the process, can be used during this phase. Statistical rationale of the number of process runs, and number of parts to be included are a critical factor to ensure the data output is normalized and representative of the operational process run of product.

Performance Qualification (PQ): PQ establishes by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements. PQ considerations include:

- Actual product and process parameters and procedures established in OQ
- Acceptability of the product
- Assurance of process capability as established in OQ
- Process repeatability, long term process stability

Challenges to the process will simulate conditions that will be encountered during actual manufacturing. These challenges will include the range of conditions as defined by the various action levels allowed in written standard operating procedures as established in the OQ phase.

The challenges will be repeated enough times to assure that the results are meaningful and consistent. Statistical rationale of number of runs and parts to be included is a critical factor to ensure the data output is normalized and representative of the operational process run of product.

Process and product data will be analysed to determine what the normal range of variation is for the process output. Knowing the normal variation of the output is crucial in determining whether a process is operating in a state of control and is capable of consistently producing the specified output.

Appropriate measures will be taken to eliminate controllable causes of variation. Eliminating controllable causes of variation will reduce variation in the process output and result in a higher degree of assurance that the output will consistently meet specifications.

As part of the Zimmer Biomet project concerning validation, a process that is validation will have ongoing process monitoring process in place. Process monitoring is defined within the FDA Code of Federal Regulations (CFR) and Global Harmonization Task Force (GHTF) now known as International Medical Device Regulators Forum (IMDRF) requirements for validations.

- **Process monitoring is within FDA requirements for validation 21 CFR 820.70.b**
  - Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.
- **Process monitoring is within GHFT Process Validation Guidance monitoring and control section 6.1**
  - Trends in the process should be monitored to ensure the process remains within the established parameters.
  - When monitoring data on quality characteristics demonstrates a negative trend, the cause should be investigated, corrective action may be taken and revalidation considered.
- **Established process monitoring plan, including statistical rationale for sample planning**
  - CTQ focused, at a minimum
  - Information within the PFMEA that includes special processes
  - Control Plan defines the requirements.

First Article Layout (FAL) Inspection Submission: The FAL requires that all identified features and characteristics on the design specification be inspected and verified prior to production. Actual measured values will be recorded as opposed to general statements of conformance or other notations simply indicating acceptance unless approved in advance with Zimmer Biomet Supplier Quality.

A separate submission is to be completed for each Zimmer Biomet part number unless otherwise specified by the Zimmer Biomet purchase order. For parts that are required to be shipped to Zimmer Biomet for specified verification, the part will be segregated and marked appropriately.

Production Process Controls

Process control involves ensuring a process is predictable, stable, and consistently operating at the target level of performance with only normal variation. Mechanical, optical, or electronic systems are used to maintain the desired output. A process control system is comprised of tools, methodologies, testing devices, standards, computer software, data collection instruments, control charting, data output, processes, work instructions, procedures, production and inspection equipment etc., employed to maintain or manage a manufacturing or production process.

Process controls selected for monitoring/controlling manufacturing processes and product characteristics will be those widely accepted by industry and capable of demonstrating quality system effectiveness.

Demonstration of process capability is required to establish that the process is stable (under statistical control) prior to performing ongoing capability studies using CpK &/or PpK process capability indices. Objective evidence of process stability will be provided.

When demonstrating process capability, objective evidence will be provided to show that acceptance of nonconforming product cannot happen. Capability study parts will be run through the planned production system as verification.

As an exception to normal process performance capability data, a 100% automated and capable inspection system along with potential sources of data (such as defect rates) can be used to meet this requirement and will be demonstrated that only conforming product be accepted. This option is to be exercised only when other options have been exhausted.

Reference List of Special Processes Requiring Validation or 100% Inspection as defined in the production transfer process (Representative list for consideration during control plan creation below).

Special Process	Validation Requirements	Process Monitoring
Test Methods (i.e., NDT testing, mech. Testing)	IQ and Test Method Validation (TMV)	N/A
Welding	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Injection Molding	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Plastic Bonding/Molding	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Compression Molding	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.

Special Process	Validation Requirements	Process Monitoring
Extrusion	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Cross Linking (UHMWPE)	IQ/OQ/PQ	Lot based monitoring
Sterilization	IQ/OQ/PQ	Lot based Dose Audit
Final Cleaning	IQ/OQ/PQ	Quarterly process monitoring per 4N.02 specification
Biological Upgrade	IQ/OQ/PQ	Quarterly process monitoring per 4N.02 specification
Sealing/Packaging	IQ/OQ/PQ	Statistically valid sample size per lot based upon risk and process performance in compliance with ISO 11607 standards. TMV required for peel test, bubble test and visual test.
Thermal Processing (i.e. Forging and Assembly)	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Shot Peening (Affects Mechanical Properties)	IQ/OQ/PQ	Lot based monitoring for mechanical properties.
Heat Treat	IQ/OQ/PQ	Lot based monitoring for mechanical properties.
Casting	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Hipping	IQ/OQ/PQ	Lot based monitoring for mechanical properties.
Sintering	IQ/OQ/PQ	Lot based monitoring for mechanical properties.
Annealing	IQ/OQ/PQ	Lot based monitoring for mechanical properties.
Passivation / EP	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Coating (i.e. anodization,)	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Plasma Spray / PVD	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Utilities such as Electrical, Air and Water System	IQ/OQ	Routine monitoring, minimum of monthly testing
Software Controlled Processes for automation CNC programs (lights out processes) and where CNC programs are stored within the machine.	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Aseptic Processing	IQ/OQ/PQ	Monitored and controlled in compliance with ISO 13408-1 Aseptic Processing Standard.

Special Process	Validation Requirements	Process Monitoring
Automated Calibration	IQ/OQ and Test Method Validation	Annual calibration of the machine
Mass Finish, such a bead blast when a RA finish is specified	IQ/OQ/PQ	Lot based monitoring
Sanitization	IQ/OQ and Test Method Validation	Lot based monitoring of vessel
Formulations	IQ/OQ/PQ	Lot based monitoring
Unique Filtration, such as particle size requirements	IQ/OQ/PQ	Lot based monitoring for particle size
Filling where homogenization is required	IQ/OQ/PQ	Lot based monitoring for homogeneity
Dipping where homogenization is required	IQ/OQ/PQ	Lot based monitoring for homogeneity
Mixing `where homogenization is required	IQ/OQ/PQ	Lot based monitoring for homogeneity
Wave/Hand Soldering	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Part Marking using Laser Etch / Chem. Etch	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Final Package Labeling	IQ/OQ/PQ	Statistically valid sample size per lot, based upon risk and process performance.
Lyophilization	IQ/OQ/PQ	Lot based monitoring

Acceptance Activities

Incoming Acceptance: Each manufacturer will establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities. Supplier will document acceptance or rejection of incoming product.

In-Process Acceptance: Supplier will I have in-process acceptance procedures to ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or until necessary approvals are received.

Final Acceptance: Supplier will have procedures for finished product acceptance to ensure that each production unit, lot, or batch of finished product meets Zimmer Biomet's acceptance criteria. Finished product will be adequately controlled until released.

Records

Quality and DHRs: All records of the quality system and manufacturing records will be maintained at the manufacturer or at other locations that are reasonably accessible to the responsible Zimmer Biomet officials. These records, including any not stored at the inspection location, will be made accessible to responsible officials of Zimmer Biomet when requested. The records will l be legible and will be stored so as to prevent loss and minimize deterioration. Records stored in automated data processing systems shall be backed up.

Record retention period: All records will be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 10 years from the date of release for commercial distribution by Zimmer Biomet.

Purchasing Controls

Supplier will establish and maintain controls on the purchase of components used in the manufacture of product to ensure conformance to specified requirements, including controls such as dimensional inspection, analytical testing and/or visual inspection of packaging, labeling, and shipping containers.

Supplier will maintain documentation that clearly describes the quality requirements for components, and will require component sources to notify the supplier of all proposed changes in component manufacturing prior to making any change. As part of supplier change notification requirements, Zimmer Biomet will participate in the review and approval of all component source changes.

If a supplier subcontracts a portion of its manufacture or inspection of components to sub-tier suppliers the requirements, including change control, defined in this document will be furnished to those suppliers, with Zimmer Biomet knowledge and approval, through purchase order requirements. The supplier remains responsible for all acts or omissions of the sub-tier supplier with whom it contracts.

Zimmer Biomet has a specific process for implantable raw material supplier controls. Supplier's that are part of this specific process will be required to provide evidence their implantable raw materials source is part of this process. Zimmer Biomet site(s) will define these requirements to supplier's where these requirements apply.

Quality Agreement

In addition to the requirements contained in this Supplier Quality Guidebook, Zimmer Biomet Sourcing and Supplier Quality will determine if a Quality Agreement is needed between Zimmer Biomet and the supplier. If the need is determined, Zimmer Biomet expects that the supplier will cooperate to put this agreement in place.

A Quality Agreement or Contract outlining the supplier specific quality requirements must be in place for all finished product manufacturing. Other products will be governed by their respective supplier quality requirements, which may be in the form of Zimmer Biomet Print Specifications/Procedure Document, Supply Agreement, Purchase Order.

Certified Part Program

Where allowed, Zimmer Biomet's respective divisions will administer a Certified Part Program on the basis of individual part numbers, product families, for overall Supplier performance. Where implemented, Certified Part program applies to material and components released for production that ship to a particular Zimmer Biomet location. Certified Part program typically does not include pre-released parts, samples, prototypes, pilot fabrication runs, first articles for new tooling or processes, and other low-volume applications.

Zimmer Biomet reserves the right to inspect any product upon receipt or at any other time, due to criticality or any other factor.

Benefits of a Supplier Certified Part program for Zimmer Biomet and Supplier are as follows:

Quality

- Patient focused risks will be communicated to suppliers based on CTQ requirements, therefore inspection plans will be focused
- Inspection sampling to be determined by the risk mitigated output of the process
- Process decisions are risk based utilizing statistical applications

Cost

- Inspection sampling to be determined by the output of the process to increase production and reduce production cost
    - Increase throughput leads to better delivery timing and reduces wait waste
    - Reduction of inspection will reduce the cost of inspection
    - Reduce cost of rework
    - Reduction or elimination of NCRs
- The certification status will create a preferential tier for suppliers competing for new business
- Success leads to Dock to Stock and Supplier Self-Certification with chosen preferential tier suppliers

Delivery

- Reduction of lead times
- Streamline the change management process
    - Creates a baseline for a product family will lead to quick turnaround time on Supplier Change Requests
- Make the right product at the right time, inventory management

To be considered for Certified Part program, the product must meet the following requirements:

- Will be an approved Zimmer Biomet Supplier
- Will meet Zimmer Biomet Certified Part process requirements
- The Supplier will not be rated as having unacceptable product quality performance, including field actions within last 6 months, with appropriate corrective action closure.
- No open and delinquent corrective action requests for the part number (or products from the same family)

The Supplier's Certified Part privilege can be suspended when any of the following, but not limited to, if conditions occur:

- A part number is detected as non-conforming
- Zimmer Biomet is made aware that the Supplier has a major non-conformance related to a second or Strategic Alliance Partners quality management system audit
- Confirmed supplier caused field action for the part number/family
- When results or audit evidence show the Supplier is not following their approved Control Plan or related work instructions

Generally, the suspension process is as follows:

- Zimmer Biomet Sourcing and Supplier Quality Engineering will notify the Supplier that their Certified Part privilege has been suspended.
- Zimmer Biomet will issue a request for corrective action to the Supplier.
- The suspension will end when the Supplier satisfies the conditions outlined in the section above or Zimmer Biomet removes the supplier fully from the Certified Part program.

6.2.7.5 Delivery, Measurements, and Monitoring

Zimmer Biomet uses a risk-based material activity acceptance process that establishes acceptance methods to determine if purchased material lots are acceptable for production. The acceptance criterion is based on the design inputs and outputs. This information is then translated into CTQ characteristics. CTQ characteristics will be provided to the supplier to help establish their internal process control plans. The supplier will be responsible for ensuring conformance to all characteristics, but will place importance on all CTQ's, including statistical data for ongoing process monitoring.

- Zimmer Biomet reserves the right to inspect/test any product/material to their applicable specifications, performance, or reliability requirements to verify their suitability of use. Suppliers are expected to work with Zimmer Biomet to resolve discrepant materials and to handle material returns in a timely manner.
- Material lots are accepted / rejected through sampling inspection of CTQs according to acceptance criteria determined by risk output from the DFMEA and/or supplier process capability.

Nonconforming Product: Supplier will establish and maintain procedures to control product that does not conform to Zimmer Biomet specifications. These procedures will address the identification, documentation, evaluation, segregation, and disposition of nonconforming product, including the need for an investigation, which is to be documented. At no time will a supplier knowingly ship nonconforming product without specific prior approval by Zimmer Biomet.

- Supplier will have control systems in place to prevent nonconforming product from being integrated with conforming product. In the event these systems fail and nonconforming product escapes through the supplier acceptance process, the supplier will immediately notify the Zimmer Biomet Sourcing contact person in order to allow Zimmer Biomet to investigate and take containment action. Supplier will fully cooperate in any investigation of containment action(s).
- Supplier will have procedures covering disposition of nonconforming product. Reworked product will include documentation of reviews and decisions, as well as the production and inspection requirements used to ensure parts are conforming. Nonstandard rework needs to be approved by Zimmer Biomet before shipment.

- In case of nonconforming product that is discovered at Zimmer Biomet, or which potentially causes a field action or recall, the supplier could incur a monetary penalty and maybe disqualified as a supplier. Non-conforming supplied product will result in Zimmer Biomet debiting the supplier for the returned product sent to Zimmer Biomet.
- Rework is defined as additional operations that are not part of the basic production process flow, which will bring product in full compliance with applicable drawings and specifications.

Instructions for rework, including re-inspection requirements, will be accessible to and utilized by the Suppliers appropriate personnel.

All reworked materials will be re-inspected in accordance with Zimmer Biomet specification requirements. Any approved rework will be documented and maintained within the supplier's DHR file. Any unapproved or undocumented rework is not acceptable.

The Supplier may also be required to provide the following:

- Identified rework area
- Written rework instructions
- Written rework inspection/test instructions
- Acceptable standards where applicable

Supplier Monitoring Through Performance: Measurement, analysis, and improvement are the processes of planning, defining, and using performance metrics for products delivered to Zimmer Biomet. These performance metrics determine the current level of performance, drive continuous improvement activities, and monitor performance levels. Statistical tools will be applied to measure the performance metrics on processes and products, but also to measure supply chain performance. Supplier will define, plan, and implement measurements where processes affect the quality of products or services that Zimmer Biomet receives.

Supplier Monitoring Through Audits: Zimmer Biomet may choose to audit the supplier's or sub-tier supplier's manufacturing and quality systems to ensure compliance with quality requirements., It is expected that during such audits Zimmer Biomet will have reasonable access to observe the supplier's or sub-tier supplier's processes.

- Facility, manufacturing, and quality control processes.
- Manufacturing and quality control records.
- Quality Systems and all analytical and manufacturing documentation related to product.
- The supplier will conduct internal audits to ensure compliance with its quality system.

Supplier will utilize appropriate packaging for shipments to prevent damage and contamination during transit. Supplier will be given guidance by Zimmer Biomet on the need for a certification of conformance, along with the document requirements for them to provide proper certification of conformity with each lot. Certification will include at minimum the following:

Supplier Certificate of Conformance/Analysis Requirements for Shipments to Zimmer Biomet

Certificates of Conformance and/or Certificate of Analysis (COC or COA)

A signed COC and or COA by the Suppliers head of Quality or a company officer (or their authorized delegate) will be furnished with each shipment to Zimmer Biomet attesting that all products and/or services delivered are in compliance with all contract requirements.

All COC's and/or COA's must be in the English or Zimmer Biomet local language requirements.

NOTE: If a Strategic Alliance Partner supplies to Zimmer Biomet and Zimmer Biomet's is the Distributor and the Alliance Partner controls the DMR then that Alliance Partner will be required to provide (at a minimum) a COC that references they own the DMR

The contents of the COC and/or COA are dependent upon the nature of the product being purchased as follows:

		Type of purchased product:		
COC and/or COA Section applicable:		Implant/ Implantable Raw Material	As Purchased / Catalog (e.g.: chemicals/screws)	Instruments
	A	X	Zimmer Biomet and / or Supllier Part #	X
	B	X	X	X
	C	X	X	X
	D	X	If applicable	X
	E	X	If applicable	X
	F	X	If applicable	If applicable
	G	X		
	H			X
	I	X	X	X
	J	X	X	X

The COC and/or COA Sections:

A. Zimmer Biomet part number

B. Zimmer Biomet purchase order number

C. Quantity

D. The drawing number and revision number (note: can specify on PO for As Purchased/Catalog items)

E. Description of materials used and Heat/Batch/Lot numbers used listed on C of C or provide Material Certs linked to COC. (lot number - when Zimmer Biomet supplied)

F. Special process(s) (e.g. Heat Treatment, Passivation, EP, Sterilization, Anodize, etc.), Provide traceability for the process:

   i. In-house – No extra certs required if identified on COC

   ii. External – Copy of the 3rd party cert linked to COC and/or COA

   NOTE: Heat Treat will require hardness results on a Cert. Suppliers are to use the same method of testing as indicated on the drawing.

G. Applicable Zimmer Biomet Implantable grade:

   i. Metals/Alloys: Need melt source by location, intermediate contract processing by location, and finish working by location. In addition melt certificate and mill certificates will be required. The COA will identify the mill sub-contractor supply chain, not acceptable is a supplier copying and pasting to make one certificate

   ii. Plastic Material will include a Certificate of Analysis or equivalent

H. Other materials: COC and/or COA or equivalent.

   i. Supply Chain requirements for implantable grade materials do not apply when material is used to manufacture instruments; requirements on the PO / print will be used for the COC and/or COA.

I. Statement of conformance to all Zimmer Biomet specifications

J. Approving signatures or electronic name of person of responsibility. All signatures or signature blocks will legibly show the name and title of the signatory.

NOTE: Any hand written information required for traceability or acceptance must have the printed name, signature and date. If certification is not received or does not contain the required information, the material will be considered nonconforming. Zimmer Biomet has the right to independently check the data reported by the supplier. Any issues will be resolved jointly.

6.2.7.6 Feedback and Communication

Communication

Fundamental to the partnership between Zimmer Biomet and its suppliers is a willingness to collaborate and communicate effectively at all levels. Open and direct access to personnel and facilities is expected. Information exchange will include the following areas:

- **Quality Data:** Traceability and other processing data available to Zimmer Biomet when addressing quality or compliance concerns
- **Strategic Planning:** Executive level communications to ensure alignment of vision, strategy, and execution, including strategies regarding supplier locations, strategic technology investments and capacity investments
- **Commercial Initiatives:** Business planning to meet material cost, supply agreement, forecast, purchasing, and logistics requirements
- **New Product Development:** Product roadmap, technology integration, and next generation product research and development
- **Sustainability Initiatives:** Sustainability projects/initiatives performed

Supplier Quality and Compliance Signals

Supplier quality signals are derived from receipt of nonconforming material, Supplier Quality System Assessments, or any other quality signal requiring action. Zimmer Biomet uses internal CAPA tools, as well as the suppliers' corrective/preventive action system to address and rectify quality and compliance signals. Supplier commitment to timely acknowledgement of issues and implementation of solutions is critical to the business relationship as a whole.

Supplier Scorecard

Supplier Performance Evaluation-Suppliers are monitored by Zimmer Biomet using established Key Performance Indicators (KPIs), which could include but not limited to, lot/piece yield, SCARs, supplier FDA 483(s), supplier cause Health Hazard Evaluations (HHED/HHE) and / or delivery. Zimmer Biomet holds established meetings on a periodic basis as part of a supplier review board process to discuss supplier's performance during the established timeframe. The output of the supplier review board is used to determine further actions needed for suppliers not meeting the established Zimmer Biomet performance requirements, up to and including supplier disqualification.

Supplier Corrective Actions

Supplier Corrective Actions-Supplier will establish and maintain procedures for implementing a CAPA system in substantial compliance with industry standards and Quality Management System requirements. When a supplier receives a SCAR from Zimmer Biomet, the supplier corrective action commitments will be tracked within the supplier CAPA system.

When a SCAR is requested by Zimmer Biomet, a target timeline is established for the supplier to provide their action plan to Zimmer Biomet. The action plan will be tracked through the Zimmer Biomet SCAR process. Zimmer Biomet Supplier Quality Engineer will be responsible for reviewing and approving the proposed supplier SCAR action plan and the proposed effectiveness criteria for the corrective actions.

If changes within the action plan or timeline extension are needed, they will be addressed and approved by the Zimmer Biomet Supplier Quality responsible for the SCAR issued to the supplier. SCAR timelines are monitored by Supplier Quality Management and SCARs that exceed targeted timelines will be noted as overdue in supplier metrics monitoring for further Zimmer Biomet Management action.

If a SCAR is issued to the supplier, the supplier is expected to provide the following documentation as part of the initial investigation if product is impacted per the targeted timing defined by Zimmer Biomet Supplier Quality SCAR request document that addresses the following:

- Problem/defect description
- Containment action performed
- Initial investigation and conclusions

For all SCARs, the Supplier will provide an action plan per the targeted timing defined by Zimmer Biomet Supplier Quality SCAR request document that addresses the following:

- Corrections, Corrective Actions, and/or Preventive Actions defined and estimated date of completion for each action
- Proposed effectiveness criteria for each Corrective and Preventive Actions

Further supplier responses may be required that will be defined by Zimmer Biomet Supplier Quality SCAR request document that addresses the following:

- Objective evidence demonstrating implementation of corrective and preventive actions as defined in the action plan
- Objective evidence demonstrating effectiveness of corrective and preventive actions

The CAPA system will include, at a minimum, the following requirements:

- Analysis of quality data (e.g. manufacturing processes, operations, quality audit records and reports, complaints, returned product) to identify root causes of nonconforming product or other quality problems.
- Containment of all affected and/or potentially affected product
- Investigation of the root cause(s) of non-conformances.
- Identification of the actions needed to correct the non-conformance and to prevent reoccurrence.
- Documentation of changes implemented to methods and procedures to correct and prevent quality problems.
- Implementation of, and recording changes to, methods and procedures needed to correct and prevent quality problems. Prior notification and approval may be required by Zimmer Biomet.
- Documentation that information regarding quality problems or nonconforming product is disseminated to appropriate quality personnel.
- Submission to management of relevant information regarding quality problems, plus corrective and preventive action.
- Documentation of activities under the CAPA system
- Document the Verification of Effectiveness (VoE) for corrective and preventive actions.

Change Management

The continuous improvement philosophy encourages process improvements; however, the supplier will notify Zimmer Biomet to collaborating outline all verification testing prior to any modification. These changes include but are not limited to: component changes, material or chemical composition changes, process changes, design changes or deviations being implemented. Changes that have regulatory impact may require FDA or other authority approval which could take 120 plus days to obtain clearance.

The supplier will complete all verifications and tests to ensure that a new process continues to yield components that meet specification prior to full implementation in production and subsequent production shipments. Approval from Zimmer Biomet is required prior to production shipments. The supplier will notify Zimmer Biomet prior to implementing any change related to products or processes involved with Zimmer Biomet products.

The following table shows examples of changes that do or do not require supplier notification to Zimmer Biomet of an impending change. This list is not all-inclusive and may be used as a point of reference, since the Zimmer Biomet-specific supplier change requirements are governed by internal procedures. Purchasing and Supplier Quality will guide the suppliers as necessary to ensure seamless changes that can be assessed and given the appropriate consideration.

SUPPLIER CHANGE TABLE FOR REFERENCE ONLY

Changes Requiring Zimmer Biomet Notification and Approval	Changes that Do Not Require Zimmer Biomet Notification and Approval
I) Production Facility-Create new building, change buildings or move product to another location.	N/A
II) Equipment-Change type of equipment or accessaory (e.g. Gamma source, Yttrium Aluminum Garnet (YAG) crystaline material for laser welding, movement of equipment within the facility that affects a validation, change or reduction of frequency/method of preventative maintenance, change machine or tool design, change of machine program, change of process parameters. Also, software changes that control quality records and/or production machine software/programs as this constitues a process change.	Movement of existing equipment within a facility that does not require re-validation per the supplier's quality system. An increase in the calibration would be needed with notification to Zimmer Biomet on or preventive maintenance frequency. Changes to software that do not interface with building or testing Zimmer Biomet product.
III) Subcontractor Change	N/A
IV) Change Inspection Requirements-All changes in inspection method, frequency, sampling methods, etc.	Changes that increase frequency or increase detect-ability, i.e. the use of equipment with higher accuracy and precision may be implemented with notification to Zimmer Biomet to follow. Traceability increase
V) Manufacturing Materials - Change Manufacturing Materials that come in contact with the Product such as coolant, machine lubricants, polishing compound, cleaning solutions, etc.	A documentation change that does not impact manufacturing methods or processing of component or finish device.

Changes Requiring Zimmer Biomet Notification and Approval	Changes that Do Not Require Zimmer Biomet Notification and Approval
VI) Manufacturing process flow - re-sequencing, changes to established router, additions/deletions, etc.	Process or equipment adjustments within a previously validated range (PQ) and which are considered routine. Changes that increase frequency or increase detect-ability, i.e. the use of equipment with higher accuracy and precision may be implemented with notification to Zimmer Biomet to follow.
VII) Rework and/or Reprocessing not outlined on the original approved Control Plan or Specification –A loop added to route product back to a previous step for the purpose of repeating work done to bring product into specification.	N/A
VIII) Forming Operations – Casting, forging, wrought operations as related to metals (e.g., changing configurations, release agents, mold, or die materials are reportable changes) and compression molding, ram extrusion, or injection molding as related to polymers.	N/A
IX) Raw Material	A material/component primary package label change that increases information and does not impact indications (note: all label/literature changes for finish medical devices do require Zimmer Biomet approval).
X) Management Change- Change in the Organizational Management structure with notification to Zimmer Biomet. These changes include, but are not limited to, changes in management with executive responsibility, or changes in management responsible for the regulatory, quality or quality systems.	N/A

6.3 Special Notes

Supplier will grant all relevant regulatory agencies, or other notified bodies, access to audit the supplier facility and/or records, with or without notification by the aforementioned organizations.

- Supplier will notify Zimmer Biomet, via written correspondence, of any inspection that is scheduled or initiated at their facility by any regulatory or notified body (FDA, competent authority or other regulating/accrediting bodies).
- Supplier will provide details of any actions (e.g. correction, removal, 483 findings, warning letter, etc.) that impact the products and/or services the supplier provides to Zimmer Biomet.

Human Tissue

Human Tissue (HCT/P's) Processing/Manufacturing Suppliers (Tissue Banks) will have an initial Quality Assessment prior to delivery of HCT/P's. Zimmer Biomet HCT/P Processing/Manufacturing Suppliers are approved by the Corporate Tissue Director according to the Zimmer Biomet HCT/P program. The ongoing monitor and control process will be procedurally governed under the Zimmer Biomet HCT/P processes.

Zimmer Biomet Distributors of HCT/P's are assessed and approved by the Corporate Tissue Director according to the Zimmer Biomet HCT/P program for storage and distribution of HCT/P's. Initial assessment is either an onsite audit or a quality assessment of the distributor's procedures, training, and applicable FDA and State licensing as applicable. The ongoing monitor and control process will be procedurally governed under the Zimmer Biomet HCT/P program processes.

Animal Tissue or Animal Derivative

Animal Tissue or Animal Derivative – As a part of compliance with the European Union medical device regulations, manufacturers of medical devices that utilize tissues of animal origin or their derivatives are required to provide evidence of compliance with European Commission Directive (EU) 722/2012, Council Directives 90/385/EEC and 93/42/EEC regarding active implantable medical devices and medical devices manufactured utilizing tissues of animal origin; Zimmer Biomet requires written confirmation from our supplier's certifying that all purchased materials meet European Union (EU) laws and regulations. These purchased parts and components include your sub-contracted processes and materials.

Applicable animals include (but not limited to) bovine, ovine, caprine, deer, elk, mink, cats, amphibian, crustacean, bird, coral, fish, reptile, mollusc – Excludes Humans (Homo Sapiens).

These materials:

- can comprise a major part of the device (e.g. bovine/porcine heart valves, bone substitutes for use in dental or orthopaedic applications, haemostatic devices),
- can be a product coating or impregnation (e.g. collagen, gelatine, heparin), or
- can be used in the device manufacturing process (e.g. tallow derivatives such as oleates and stearates, foetal calf serum, enzymes, culture media).

Zimmer Biomet has identified the following items as high risk or contact materials. This list is not exhaustive.

- Buffing/Polishing materials (e.g. soaps and abrasives)
- Lubricants and coolants
- Detergents and other cleaning materials
- Packaging materials including glues, release agents etc.
- Plastic release agents
- All products sold to Zimmer Biomet will be free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE). In addition, a letter stating this will be sent to the Zimmer Biomet purchasing representative.
- Latex Free

RoHS/Restricted Materials

- Supplier will also conform to the latest RoHS standards and certify that the products provided to Zimmer Biomet, whether component, raw material, or finished goods, will comply with the current RoHS compliance.
- Supplied product is also prohibited from containing
- bisphenol A (BPA),
- di(2-ethylhexyl) phthalate (DEHP),
- di-2-ethylhexyl-adipate (DEHA) or
- polyvinyl chloride (PVC),
- Conflict materials [columbite-tantalite, also known as coltan (from which tantalum is derived); cassiterite (tin); gold; wolframite (tungsten);] (as defined by United States Dodd-Frank Consumer Protection Act), or other.

FURLS

FDA Unified Registration and Listing System (FURLS). Owners or operators of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States are required to register annually with the FDA. Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. (See FDA 21-CFR Part 87 and the FDA.gov website.) These include parts / devices where Zimmer Biomet is the design responsible party (see 21CFR820.3 Definitions):

(l) Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Zimmer Biomet Unique Device Identification (UDI) Requirements

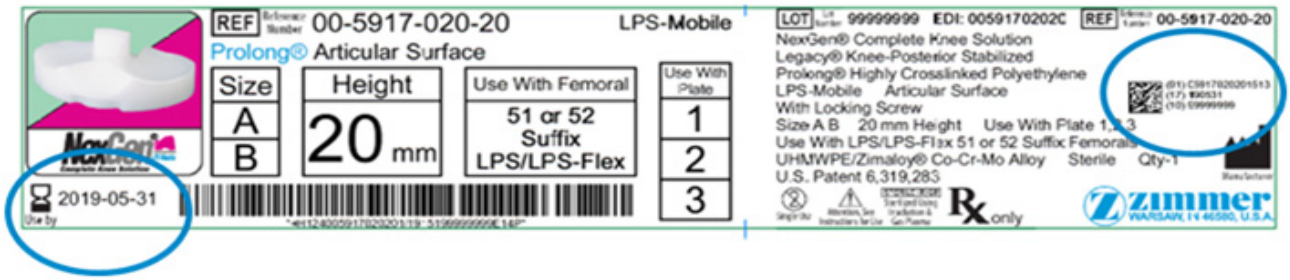
Both Zimmer Biomet and suppliers are required to meet FDA and UE MDR 2017/745 requirements for UDI through labeling and/or product marking for products sold in the US, and / or EU (European Union) and EFTA (European Free Trade Association, including Switzerland) markets as defined by: 21CFR parts 16, 801, 803, 806, 810, 814, 820, 821, 822,830, EU MDR 2017/745 and Zimmer Biomet Corporate Procedures. FDA, EU MDR, and/or Zimmer Biomet implementation dates apply.

Labels

Labels will include:

- GS1 compliant 2D (two-dimensional) barcode and Human Readable Interpretation
- For existing suppliers - UDI is simply adding the UDI to existing label information (GS1 Data matrix or GS1 128 barcode and / or EU MDR Compliant as applicable with Human Readable Interpretation and modifying date format to match UDI requirements). FDA, EU MDR and/or Zimmer Biomet implementation dates apply.
- Zimmer Biomet EDI information
- Expiration Date, and/or Manufacturing Date in the following format: YYYY-MM-DD

Sample Zimmer Biomet Unique Device Identification (UDI)-compliant label below:



Direct Part Marking (DPM)

Each medical device (instrument, implant, etc.), as defined by FDA Procedures and / or European Medical Device Regulations (EU MDR), will have a unique identifier as defined by: 21CFR parts 16, 801, 803, 806, 810, 814, 820, 821, 822,830 and Zimmer Biomet Corporate Procedures. FDA, EU MDR 2017 / 745 and/or Zimmer Biomet implementation dates apply.

Part Markings typicality includes the following:

- 2D (two-dimensional) barcode information along with Human Readable Interpretation
- Specific details (format, type, size, content, location, etc.) of specified requirements are to be included on part drawings and related corporate procedures.
- Certain exemptions (e.g. EU MDR Direct Part Marking: Anex VI Part C Sections 4.10, 6.2) for direct part marking do exist based on product / device type, packaging, size, reusability, and sterilization – These will communicated (as applicable) on Zimmer Biomet part drawings and related corporate procedures.

Master Data Management (MDM)

If the Suppler owns the Regulatory files for the medical device, the Supplier is responsible for uploading the required attributes to the FDA GUDID (Global Unique Device Identification Database) and/or the European EUDAMED as requested by Zimmer Biomet. FDA, EUDAMED, and/or Zimmer Biomet implementation dates apply.

7. Revision History

Listed below are the changes that resulted in the revision of this procedure.

Revision	Change number	Description of the change
01	342527	New document
02	395778	Update of document to reflect CP06018, Rev. 3 Document was restructured and reformatted; various minor verbiage changes; change reference to SPPA (former PPAP+); new special process and validation requirement table was added; change management table was modified
03	424174	Update section 2.2.1 – 2.2.3 to meet Zimmer Biomet new Purpose/Mission/Guiding Principles Update following sections to meet EU MDR 2017/745 requirements: UDI Requirements Direct Part Marking Master Data Management
04	467494	Update the term Third Party Manufacturers to Strategic Alliance Partners.