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PROCEDURE APPROVALS

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Global Supplier Quality Guidebook

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1. Zimmer Biomet Corporation

Zimmer Biomet History

Inspired to Innovate from the Start: Our History

Zimmer Biomet was the inspiration of Justin O. (J.O.) Zimmer, a national sales manager for a wooden splint manufacturer.

It was 1926, and aluminum, once considered a precious metal, was becoming more widely available and affordable. J.O. recognized the lightweight yet durable material's potential for transforming the splint market. When his employer rejected his idea to add a line of aluminum splints, J.O. set out on his own.

Zimmer: An idea that transformed an industry

With the help of two investors and a modest staff, J.O. launched a splint manufacturing business in Warsaw, Ind. By 1927, J.O. and his team had developed a line of 50 aluminum splints and other orthopedic products.

When J.O. presented these products at the American Medical Association's annual meeting, he completely changed the orthopedic industry. It wasn't long before the tiny startup, Zimmer Manufacturing Company, dominated the market for orthopedic equipment.

In the decades that followed, Zimmer grew steadily, expanding on its own advancements with a steady stream of acquisitions. That simple line of splints broadened into implants, surgical devices, bone cements and diagnostic and recovery solutions. The use of aluminum—revolutionary in J.O.'s time—gave way to products made from titanium, Trabecular Metal™ and polyethylenes. The company also began offering world-class medical training and education, reinforcing its commitment to clinical excellence.

Despite its expansive growth, acquisition by Bristol-Myers in 1977 and the return to an independent, publicly traded company in 2001, Zimmer and its Team Members never strayed from that initial desire to improve the quality of life for patients around the world.

Biomet: A musculoskeletal engineering powerhouse

The same year that Zimmer was acquired by Bristol-Myers, another musculoskeletal company was launched in Warsaw: Biomet. The company was founded in 1977 with just eight Team Members. The founders, all bioengineers, included Dane Miller, Ph.D., and Jerry Ferguson, who both began their careers at Zimmer. Dane would become the company's first and longest-serving CEO.

Biomet established itself from the start as a champion of biomaterials and advancements in musculoskeletal engineering. 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.

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Just as Zimmer had done decades ago, Biomet grew quickly through groundbreaking research and development, as well as strategic acquisitions. The company went public in 1982. By the end of its first decade, sales exceeded $97 million, and the initial eight Team Members had grown to 1,000. As the years progressed, Biomet gained widespread recognition for its unique corporate philosophy and culture, which focused on customer responsiveness, teamwork and innovation.

In 2007, Biomet was purchased by a private equity consortium. Explosive expansion in products and sales continued. Through it all, the company maintained its steady approach to engineering world-class products, serving its customers and viewing every patient as a member of its own family.

The launch of One Zimmer Biomet

For decades, Zimmer and Biomet introduced cutting-edge advancements in musculoskeletal health. The companies shared similar values and offered complementary solutions. The combination of the two companies was a natural fit. On June 24, 2015, Zimmer closed on the acquisition of Biomet, bringing together two global leaders of musculoskeletal healthcare.

The creation of Zimmer Biomet made the company the leading innovator in the musculoskeletal market. The company gained a combined workforce of about 19,000 Team Members around the globe serving approximately 100 countries. This pooling of unmatched talent and resources has enabled the company to accelerate the pace of innovation and build on a portfolio of thousands of patents and applications to better meet patient needs.

Looking to the future

On August 22, 2023, Zimmer Biomet announced the appointment of Ivan Tornos as President and Chief Executive Officer.

The spirit of innovation that transformed a line of aluminum splints into a global pioneer of musculoskeletal solutions is still very much alive today. Zimmer Biomet's portfolio and capabilities continue to expand through in-house research and development as well as strategic acquisitions.

As Zimmer Biomet looks to the future the focus never wavers from its humble roots. Together, Team Members are harnessing *The Power of Us* to *Alleviate pain and improve the quality of life for people around the world.*

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Zimmer Biomet Mission/Guiding Principles/Quality Policy

THE POWER OF US.

Our Mission

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

Guiding Principles

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

Corporate Quality Policy

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2. The Quality Guidebook

2.1. 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.

2.2. The quality requirements apply to the development and manufacture of all products/services supplied to Zimmer Biomet. These requirements are established through Supplier Agreement 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.

2.3. Quality Requirements are defined either 1) a stand-alone Supplier Quality Agreement (SQA), 2) a long-term supply agreement with the SQA as an exhibit, or 3) a Zimmer Biomet Purchase Order (PO).

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

2.5. 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.

3. Supplier 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.

Supplier Code of Conduct can be found on the Zimmer Biomet.com website or copying the web address into your browser:

https://www.zimmerbiomet.com/content/dam/zb-corporate/en/suppliers/global-and-nam/Zimmer-Biomet-Code-of-Supplier-Conduct.pdf

Within the Guideline you will find:

1. **Compliance with Applicable Laws, Regulations, and Industry Best Practices**
2. **Standards of Employment**: Safe Work Environment, Security, Child Labor Avoidance, Slavery and Human Trafficking, Wages and Benefits, Working Hours, Respect and Dignity, Non-Discrimination, Freedom of Association, Immigration Laws, and Reporting
3. **Ethic and Business Conduct**: Fair Dealings, Securities and Insider Training Laws, Anti-Corruption and Anti-Bribery, Conflict of Interest, Gifts and Entertainment,
4. **Sustainability and Environmental Responsibility – Business Continuity, Environmental Sustainability, Restriction of Hazardous Substance, Animal Tissues, and Conflict Minerals**

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5. **Confidentiality and Privacy**: Confidentiality and Privacy
6. **Compliance and Record Retention**: Audits and Assessments, Certifications, Corrective Action, Compliance, Consequences, Reporting Non-Compliance.

4. Zimmer Biomet Supplier Focus/Expectations

4.1. **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.

4.2. **Supplier Expectations.** It is Zimmer Biomet's expectations that:

4.2.1. Suppliers provide data to demonstrate compliance to applicable external regulations and standards.

4.2.2. Materials, components, assemblies, services and finished medical devices supplied to Zimmer Biomet meet or exceed all quality and product specification requirements.

4.2.3. The Supplier will provide written notification to Zimmer Biomet of any changes referenced in the Supplier Quality Agreement immediately using Zimmer Biomet supplier change notification process. This notification will be submitted in order for Zimmer Biomet to evaluate the impact of the change to the quality of the finished product/service. Suppliers have a compliant Quality System that meets Zimmer Biomet Supplier Assessment Requirements.

4.2.4. Suppliers review and sign a Supplier Quality Agreement (SQA) when required.

4.2.5. 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.

4.2.6. Supplier has a master validation plan established to monitor and control of process validations.

4.2.7. Supplier maintains a Device History Record (DHR) for the manufacturing and quality documentation of each lot/batch produced.

4.2.8. Suppliers support regulatory audits and unannounced audits by notified bodies.

4.2.9. 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.

4.2.10. Delivering to the Requested Delivery Date in order to maintain a 95% On-Time-In-Full (OTIF) Delivery Metric.

4.2.11. Supplier lead-time for manufacturing is to be communicated real-time to Zimmer Biomet if they change. This communication needs to go to the Buyer of the product.

4.2.12. Suppliers need to communicate capacity constraints as soon as they are identified; this communication goes to the Buyer.

4.3. **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:

4.3.1. Implement formal, management-sponsored continuous improvement initiatives. Examples include Six Sigma, Lean, or Total Quality Management initiatives.

4.3.2. Implement Statistical Process Controls (SPC) for all critical input and output process variables to enable sampling and remove 100% inspection requirements.

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4.3.3. Achieve process capabilities for all critical input and output process variables, to enable sampling and removed 100% inspection.

4.3.4. Strategic suppliers with long-term agreements are also expected to invest and keep current with the latest technologies and capabilities.

4.4. **Measurements -** Zimmer Biomet uses a variety of tools and metrics to set expectations and to evaluate suppliers' abilities to meet them:

4.4.1. Supply Agreement – this sets quality level expectations.

4.4.2. Relationship – the quality of interactions, measured by supplier responsiveness, level of support, and open/effective communication.

4.4.3. Delivery Performance – the ability to ensure an appropriate level of production/finished goods and on-time completion of services.

4.4.4. Capacity/Flexibility/Lead Time – the ability to quickly respond to changes in demand.

4.4.5. Supplier Controls – a supplier management program articulating expectations consistent with those expressed in this Supplier Quality Guidebook.

4.4.6. Business Continuity – clear disaster recovery plans addressing potential natural and man-made business interruptions (includes critical Tier 2 suppliers).

4.5. **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:

Customs 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	

5. Planning and Selection of Potential Suppliers

5.1. **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.

5.1.1. Zimmer Biomet determines the quality and product specification requirements for the product/service the supplier will meet per the DMR. Quality and regulatory requirements

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specified by Zimmer Biomet, including requirements for delivery and post-delivery of product.

5.1.2. 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.

5.2. **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.

5.3. **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.

5.3.1. 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.

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

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

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

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

5.3.2.4. **Value** - Competitive pricing, cost reduction capabilities and active participation in inventory management initiatives.

6. Finalization of Controls

6.1. Critical to Quality (CTQ) Specification Characteristics

6.1.1. CTQ's are the key measurable 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.

6.1.2. 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 with the severity of failure that would affect the customer (e.g., patient risk). The higher risk numbers will be associated to the characteristic's specification defined as CTQ.

6.1.3. 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 Supplier Production Process

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Approval (SPPA) with defined quality and process requirements. However, compliance to all the print and quality/product specifications is expected.

6.2. Supplier Production Process Approval (SPPA)

6.2.1. 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 planning and execution phases with specific requirements that will be met, and approved, before moving into the next phase.

6.2.2. 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.

6.2.3. The supplier will demonstrate conformity to those designated CTQ 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.

6.3. Key Production Control Elements of SPPA Process

6.3.1. 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.

6.3.2. 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.

6.3.3. 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.

6.3.4. 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.

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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 cases where the only method of inspection would be destructive testing, validation is required as 100% inspection would destroy all produced product, see process validation section below.

6.3.5. 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 30% error – the measurement system is acceptable.
- Greater Than 30% error – needs improvement unless approved by Zimmer Biomet Supplier Quality Engineering.

6.3.6. 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.

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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 ≥ 1.0 the process currently meets acceptance criteria
- Index < 1.0 the process may not be acceptable

For supplier performance validation (capability study) is required with acceptable results per Zimmer Biomet defined acceptance criteria or 100% inspection will be required. If supplier is attempting to reduce 100% inspection to sample planning for products defined CTQ characteristics, a successful capability study is required.

6.3.7. 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.

Zimmer Biomet defines the processes for reviewing and disposition of supplier process validations, including but not limited to manufacturing, packaging, and sterilization processes that 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 defined as 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 product transfer plan, it is the supplier responsibility to provide and adoption report that gives the rationale that the product being transferred under the new project is not a new worst-case part for the current validation.

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

6.3.8. The Three key elements of Process Validation (According to requirements found within the International Medical Device Regulators Forum (IMDRF) GHTF Study Group 3 document)

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6.3.8.1. **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)

6.3.8.2. **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.

6.3.8.3. **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.

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Process and product data will be analyzed 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.

6.3.8.4. As part of the Zimmer Biomet project concerning validation, a process that requires 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 IMDRF requirements for validations.

- Process monitoring is defined within FDA requirements per ISO 13485:2016 Clause 7: Product Realization
  - *implementation of monitoring and measurement of process parameters and product characteristics*
- 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.
- If the process does meet the capability requirements, a reduced sampling plan may be used based on process performance.

6.3.9. 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.

6.4. Production Process Controls

6.4.1. 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

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or production process.

6.4.2. 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.

6.4.3. 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.

6.4.4. 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.

6.4.5. 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.

6.5. Acceptance Activities

6.5.1. 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.

6.5.2. In-Process Acceptance: Supplier will 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.

6.5.3. 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.

6.6. Records

6.6.1. 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 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.

6.6.2. 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 15 years from the date of release for commercial distribution by Zimmer Biomet.

6.7. Purchasing Controls

6.7.1. 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.

6.7.2. 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.

6.7.3. If a supplier subcontracts a portion of its manufacture or inspection of components to sub-tier

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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.

6.7.4. 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.

6.8. Quality Agreement

6.8.1. In addition to the requirements contained in this Supplier Quality Guidebook, Zimmer Biomet 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.

6.8.2. The Quality agreement will establish defined requirements that a supplier must meet based on the type of product or technology they provide to Zimmer Biomet. At a minimum, per the ISO and FDA guidelines Zimmer Biomet must have change control requirements defined that the supplier must adhere to allow Zimmer Biomet to assess the supplier change to determine the change effects on product and quality system.

7. Delivery, Measurements, and Monitoring

7.1. 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.

7.2. 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.

7.3. 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.

7.3.1. 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 Supplier Quality 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).

7.3.2. 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.

7.3.3. 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. Return Material Authorization (RMA) will be provided within 2 business days.

7.3.4. Standard 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

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specifications.

Documented assurance that the Product shall be re-inspected using existing inspection criteria or NDT method per applicable inspection procedures including verification that the inspection or NDT method is effective for the rework process.

Product shall later meet all final specifications within current routed operations and inspections.

Non-Standard Rework: Rework that is not predefined in the product's manufacturing process documentation as part of the DMR and the approved manufacturing router.

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.

7.4. 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.

7.5. Supplier Monitoring Through Audits. Zimmer Biomet may choose to audit the supplier or the supply chain 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 or supply chain processes.

7.5.1. Facility, manufacturing, and quality control processes.

7.5.2. Manufacturing and quality control records.

7.5.3. Quality Systems and all analytical and manufacturing documentation related to product.

7.5.4. The supplier will conduct internal audits to ensure compliance with its quality system.

7.6. 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.

7.6.1. The Zimmer Biomet applicable requirements for a Certificate of Conformance (CoC) will included with all shipments of product sent to Zimmer Warsaw. At a minimum, the CoC is to include the following requirements:

7.6.1.1. Zimmer Biomet Part Number and Revision Level including all Subcomponent Part Numbers and Revision Levels.

7.6.1.2. By certifying to the Part Number and Revision on the print, you are also certifying that the product meets all Engineering Specifications designated on the print.

NOTE: It is not required to certify to each individual Engineering Specification.

7.6.1.3. Zimmer Biomet Purchase Order Number

7.6.1.4. Material Certificate of Analysis (CoA)

7.6.1.5. Applicable Zimmer Biomet Implantable grade:

7.6.1.6. 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,

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not acceptable is a supplier copying and pasting to make one certificate

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

7.6.1.8. 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

7.6.1.9. Quantity Shipped

7.6.1.10. Supplier Lot Number/Job Number/Batch Number

7.6.1.11. Zimmer Biomet Provided Gage Numbers and ID letter as applicable

7.6.1.12. Supplier Name and Number

7.6.1.13. Date

NOTE: 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**NOTE**: Commercial of the Shelf (COTS) product would not apply to these requirements

8. Feedback and Communication

8.1. 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.

8.2. 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 supplier caused recall. 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.

8.3. 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 will be responsible for reviewing and approving the proposed supplier SCAR action plan and the proposed effectiveness criteria for the corrective actions.

8.4. 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

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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.

8.4.1. 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.

8.4.2. The Zimmer Biomet change management processes will manage supplier changes, along with change control requirements defined within the Supplier Quality Agreement.

8.5. 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 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/Ps are assessed and approved according to the Zimmer Biomet HCT/P program for storage and distribution of HCT/P's. Initial assessment is an onsite audit 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, mollusk - 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 orthopedic applications, hemostatic devices),
  - can be a product coating or impregnation (e.g., collagen, gelatin, heparin), or
  - can be used in the device manufacturing process (e.g., tallow derivatives such as oleates and stearates, fetal calf serum, enzymes, culture media).

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  - that animals used for materials in the production of products DO NOT contain any items listed as endangered, threatened with extinction or subject to controlled trade in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) appendices I or II.

- 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.

Substance of Very High Concern

A Substance of Very High Concern (SVHC) is a chemical substance proposed to be subject to authorization under the REACH regulation, which might lead to restrictions of use for the substance. Criteria to propose a chemical substance to be added to the SVHC list include that the substance is a Carcinogenic, Mutagenic and/or Reprotoxic (CMR), Endocrine Disruptors (ED) and/or Persistent, bioaccumulative and toxic substances (PBT)/ Very Persistent and very Bioaccumulative substances (vPvB) substance.

- Notably, a Safety Data Sheet (SDS) will include any SVHC that is contained in a mixture of substances at 0.1 % w/w. Thus, the information if a SVHC is contained in a contact material is available in the SDS. The official candidate list of substances of very high concern for authorization is available on the homepage of the European Chemicals Agency (ECHA), Lubricants and coolants.

Carcinogenic, Mutagenic and/or Reprotoxic (CMR) substances are hazardous substances with severe toxicity. Carcinogenic substances can cause and promote cancer. Mutagenic substances increase the occurrence of genetic mutations. Reprotoxic substances cause adverse effects on sexual function and fertility, developmental toxicity in the offspring and effects through or via lactation.

- EU classification of CMR substances include categories:
  - 1 A (known to have CMR potential for humans, based largely on human evidence),
  - 1 B (presumed to have CMR potential for humans, based largely on experimental animal data), and
  - 2 (suspected to have CMR potential for humans).

Notably, the information on CMR substances including their category will be listed in the SDS.

Endocrine disruptors have been defined as exogenous substances that alter function(s) of the endocrine (hormone) system and consequently cause adverse health effects in an intact organism or its progeny, or (sub) populations.

- Currently, no comprehensive list of EDs with serious effects to human health is available. EDs will be identified in accordance with Article 59 of Regulation (EC) No. 1907/2006 until further legislation is available.
- Notably, Known EDs with serious effects for human health are of often included in the SVHC list or CMRs of category 1A or 1B. Packaging materials including glues, release agents etc.

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) is a regulation adopted to improve the protection of human health and the environment. REACH includes among else the regulations regarding RSL and SVHC substances.

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),

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- 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 EU 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:

- Compliant 2D (two-dimensional) barcode and Human Readable Interpretation
- For existing suppliers - UDI is simply adding the UDI to existing label information (e.g. 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

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 be communicated (as applicable) on Zimmer Biomet part drawings and related corporate procedures.

Master Data Management (MDM)

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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.

9. References

FDA – Food and Drug Administration 21-CFR-820 codes of federal regulation requirements (see FDA.gov)

FDA Unified Registration and Listing System (FURLS) – 21-CFR-820-870 (see FDA.gov)

FDA 21-CFR Part 87 (see FDA.gov)

AIAG – Measurement Systems Analysis Manual 4th Edition

AIAG – Production Part Approval Process Manual 4th Edition

AIAG – Statistical Process Control Manual 4th Edition

IMDRF – IMDRF International Medical Device Regulators Forum Study Group 3 for Supplier Management and Process Validation

UDI – Unique Device Identification 21-CFR 820-830 and 21-CFR-820-831 (UDI) per FDA.gov

FURLS - FDA 21-CFR Part 87 found on the FDA.gov website

Dodd-Frank Consumer Protection Act via FDA.gov website

ISO 13485 Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes

EU 2017/745 (MDR): European Medical Device Regulation

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) appendices I or II

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