Quality Elements for Suppliers of Products or Services to GMP Regulated Companies

A joint venture between:

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1. Introduction

Medical products are items used to diagnose, treat, cure, mitigate or prevent disease in patients. These include pharmaceutical products and medical devices. The manufacture of medical products that are used in the United States, and in many other countries, are regulated by Good Manufacturing Practices (GMP) and Quality System Regulations (QSR). These regulations, which are nearly identical in many countries, cover not only the manufacture of finished products, but may also encompass starting and intermediate materials and related services that are a part of the supply chain for those medical products. The result is that many medical product manufacturers require products or services from providers who adhere to GMP/QSR (collectively, "GMP") as well.

Adoption of GMP can provide advantages to suppliers, including expanded market opportunities with the added benefit of increased profitability through improved manufacturing techniques.

a. Purpose

The purpose of this document is to outline those basic GMP elements that may be required of suppliers whose products or services eventually enter the supply chain for the manufacture and delivery of regulated medical products.[1] When established and followed, these GMP elements help to assure product quality, minimize compliance risk to the manufacturer, and protect patients. This document addresses the risks involved regarding the intended use vs. actual use of products and services.

b. Scope

This document applies to all suppliers of products or services that have an impact on GMP processes within the supply chain for commercial manufacturing and delivery of regulated medical products.

The GMPs referred to within the document are related to regulated medical products manufacturing. When established and followed, these GMP elements help to assure product quality, minimize compliance risk to the manufacturer, and protect patients.

The target audience for this report is suppliers of starting and intermediate products and related services within the supply chain used by manufacturers of medical products subject

[1] Disclaimer – As written, GMP regulations describe minimum standards. As such, they are subject to interpretation. Applicability and compliance with GMP regulations and enforcement by Health Authorities may vary from country to country. GMP regulations should be considered as minimum requirements as suppliers may be subject to Quality Agreements with their respective customers that may differ, and in fact exceed those stated here.

to GMP regulations. This document is written with a focus on the supplier, but explanations and expectations of the customer are also described.

c. Key Terms

Term	Explanation
Applied Use	How the product is used by the customer.
Compliance	An organization's adherence to law, regulations, guidelines, and specifications relevant to its business.
Customer	Manufacturer of medical products subject to GMP regulation by country or countries in which products are sold.
Documentation	Information, recorded either electronically or handwritten, that is used to provide instruction, information, or evidence of an action or a result.
FMEA	Failure Mode Effects Analysis - a technique used to identify all possible failures in a design, a manufacturing or assembly process, or a product or service.
FTA	Fault Tree Analysis - a step-by-step approach used to identify all possible failures in a design, a manufacturing, or assembly process, or a product or service.
GMP	Good Manufacturing Practice - a system for ensuring that products are consistently sourced, produced, and controlled according to documented quality standards.
HACCP	Hazard Analysis and Critical Control Points - an internationally recognized system for reducing the risk of safety hazards in food.
Intended Use	The use for which the product was designed or produced. This may or may not be the way in which the customer actually uses the product.
Materials	The component(s) used in the manufacture of a product.
Medical Products Manufacturer	Organization that produces medical products or components used to make medical products.
Medical Product	Medical products are items used to diagnose, treat, cure, mitigate or prevent disease in patients. These include pharmaceuticals, medical devices, diagnostic equipment and supplies, surgical instruments.
Product	Any item sold by the supplier to the customer.
Qualification	A documented process of assurance that the specific system, premises, or equipment is able to achieve its predetermined intended use.
Quality Agreement	A Quality Agreement is intended to clarify exactly what is expected of both parties (supplier and customer), and who will be responsible for virtually all aspects of production. Quality agreements are required by EU GMPs (EU GMPs 7.10 – 7.15) , and ICH (Q10 §2.7) for pharmaceutical products, and medical devices (21CFR820.50), EU MDR 2017/745 and ISO 13485

Quality Assurance	That part of quality management focused on providing confidence that quality requirements will be fulfilled. Many companies have a separate department devoted to quality assurance.
Quality Control	That part of quality management focused on fulfilling quality requirements. This is often accomplished by testing starting materials, in-process materials, and final product samples to determine if product specifications are being met.
Quality Unit	The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, quality, form, fit or function of the material or service provided.
Risk	The probability or threat of damage, injury, liability, loss, or any other negative occurrence that is caused by external or internal vulnerabilities that may be avoided through preemptive action.
Service	Any non-product offering provided by the supplier to the customer.
Supplier	Any party that provides a product or service to the end-user.
Supplier Agreement	An agreement between a supplier and a buyer for supply and purchase of products. The agreement specifies the terms upon which the parties agree to supply and purchase products from each other. Although different, the Supplier Agreement may refer to a Quality Agreement.
Unregulated supplier	A supplier who is far enough removed from direct sale to the customer such that their products or services are not subject to all GMP or other regulatory requirements.
Validation	Process used to establish documented evidence that a specific system, process, or facility will consistently produce a product meeting predetermined specifications and quality attributes.
Vendor	Any person or company that is not the original manufacturer that offers either a product or service for a fee.

2. Why is it Important to Industry?

Although medical product manufacturers commonly expect their suppliers to comply with regulations to which they are subject, not all products, materials or services supplied to medical product manufacturers need to meet GMP requirements. Further, not all suppliers are aware of how their products will be utilized by their customers. As such, intended use, design-use, and applied use by the customer are not always in alignment with the supplier's own product or service specifications. This misalignment is a common occurrence that can result in conflict between suppliers and customers and in some cases, may lead to regulatory action for non-GMP compliance against the end-user.

To ensure that product and service suppliers comply with GMP, medical products manufacturers often specify in Quality Agreements the extent to which GMP compliance is required. These agreements can include the right to audit supplier sites in order to examine

the suppliers' quality systems for assurance that they are reliably controlled and maintained up to and including full GMP compliance.

Issues to consider:

- What is the country of origin?
- Is the applied use as well as the intended use considered?
- Are the materials Conflict Mineral compliant?
- Is there a TSE/BSE certificate?

3. Explanation of Principles

In an increasingly competitive global marketplace, gaining and maintaining customer confidence is critical. An effective way of accomplishing this is through the adoption of GMP principles.

a. Although GMPs may appear complex and limiting, when the fundamental principles are appropriately applied, the outcome is beneficial to both the customer and the supplier.

b. Application of GMP principles to all phases of the manufacturing process ensures that the product is made in a controlled and consistent manner. This includes documented processes, procedures, and test results.

c. An additional benefit of GMP principles is increased manufacturing efficiencies that result from optimized and improved process controls, reduced shutdowns and work stoppages. The GMP requirement to review and assess process changes before implementation can minimize risk associated with unproven change and can enable continuous improvement. Application of these concepts can result in greater continuity and consistency of supply that meets end-user requirements.

GMP compliance may increase opportunities in the marketplace for suppliers and may provide an advantage over competitors: when customers know that their suppliers comply with GMP they may be willing to include their products into their processes.

4. Ten Key Principles/Elements of GMP

A supplier may have a quality management system in place, such as ISO 9001 or other relevant system(s). In addition to or notwithstanding the absence of such systems, the following ten (10) key principles should be considered and implemented.

I. Document Manufacturing Processes [21CFR 211.100(a), 211.186, ICH Q7 §6.4 and 6.5]

a. Develop detailed, written procedures that are followed by personnel in a step-by-step fashion to ensure that products are manufactured consistently.
b. The procedures shall document manufacturing standards and processes, to ensure that a job, process, or procedure is performed the same way each time, with each step to be followed as set out in the written instructions.
c. Critical processing steps, such as weights, lot numbers, temperatures, mix times, test result, etc., are to be documented at the time of performance on the production record. These results must include time, date, and signature of the individual who performed and recorded the service or activity.
d. Companies shall establish and maintain a documentation and record control program.

Best Practices for Manufacturing Process Documentation:

- Production records should be reviewed and approved by the quality unit before use
- The use of an organized numbering system and versioning makes documents easier to control, access, and retrieve.
- Critical process parameters should be captured in sufficient detail on production records to facilitate troubleshooting in the event of off-specification product.

II. Investigate Deviations [21CFR211.100(b), ICH Q7 §2.3 and 6.5]

a. Any deviation from written procedure or from expected results must be investigated and that investigation must be documented. A deviation investigation shall include the following:
    i. Effect of deviation on affected product, service or process for affected batch.
    ii. Effect of deviation on safety or quality of batches prior to or following the affected batch.
    iii. A corrective / preventive action (CAPA) plan to reduce or eliminate the potential for deviation to reoccur.

iv. Trending to determine deviation frequency and effectiveness of preventive actions.

b. The investigation report must identify the deviation, investigate the cause, and identify the effect on product, service or process. The report should be reviewed and approved by the quality unit.

Best Practices for Investigating Deviations:

- Internal audits can be used to verify that approved procedures are being properly followed.
- Deviations should be tracked, trended and investigated to prevent future reoccurrences.
- Corrective and preventive actions should be viewed as opportunities for continuous improvement

III. Follow Good Documentation Practices [21CFR 211.100(a), ICH Q7 §6.5]

a. Companies shall have procedures in place detailing good documentation practices which include how corrections, when necessary, are to be annotated. These procedures must follow "A L C O A" principles:
   i. **A** - Attributable – documentation should clearly demonstrate who performed the activity, and who observed and recorded the activity (this may be more than 1 person).
   ii. **L** - Legible – as entered, information should be easily understood, permanently recorded, and have original entries preserved (not obscured through erasure, white out, or cross out).
   iii. **C** - Contemporaneous – information should be recorded at the time the activity was performed. Date and time entries should never be back dated or entered in advance.
   iv. **O** - Original – also known as primary or source data, is the medium in which the data was recorded for the first time. This could be a database, a form, or a notebook. Original data should never be transcribed.
   v. **A** - Accurate – recorded information should be free from error, complete, truthful, and a true reporting of the actual observed result.

b. Processes and procedures shall be put in place to ensure the integrity of data.

Best Practices for Maintaining Good Documentation Practices:

- Mistakes happen. Do not try to make it look like they did not occur, instead, document and correct them.
- Review any document or record and ask the question 'Will I or someone that was not involved in the record understand what this means 6 months from now?
- Obsolete records should be disposed after a period of retention in a way to ensure confidentiality to any related parties where applicable.

IV. Validate Processes/Qualify Facilities and Equipment [21CFR211.42, 211.67, 211.68, ICH Q7 §4, 5]

a. Procedures shall be in place that define how equipment (including manufacturing and analytical), utilities (including HVAC, purified water, steam, compressed air), are qualified to perform as intended. Procedures shall be in place that define how processes/procedures (including manufacturing, cleaning, test methods, software systems) are validated.
    i. Validation of processes / qualification of facilities and equipment is achieved through a prospectively documented plan consisting of written procedures intended to ensure that product quality and consistency are carried out according to a plan approved by the quality unit prior to execution.
    ii. All validation / qualification activities shall include all tests and documentation required along with clearly delineated pre-defined acceptance criteria.
b. All validation and qualification projects require documented evidence that the validation / qualification was effective.
c. Electronic systems (Computer Systems) shall be appropriately validated based on a risk assessment to ensure the accuracy and integrity of any originally collected data.

Best Practices for Validation of Processes/Qualification of Facilities and Equipment:

- Equipment shall be qualified prior to use.
- Utilities such as HVAC and purified water systems may be affected by seasonal changes. Seasonal fluctuations should be considered as a part of qualification activities.
- Develop a check list for tests to prove that the equipment is working properly.

V. Set-up, Cleaning, and Maintenance of Facilities and Equipment [21CFR211.58, 211.65, 211.67, ICH Q7 §4.7, §5.2]

a. Proper design and set-up of facilities and equipment are important aspects of a good quality management system. A good design can integrate productivity, product quality, and employee safety.
   i. Facility layout should reduce the chance of introducing adulterants and cross contamination from other processing lines. Layout should facilitate the flow or sequence of operations from starting materials to finished goods.
   ii. Temperature, humidity, particulate matter in air, purified water, lighting, ventilation, and pests (including microbes, yeasts and molds) should be controlled as necessary to minimize impact on product quality.

b. All facilities and manufacturing equipment should be maintained, controlled, and monitored according to written procedures to ensure that they are operating within the operational and performance parameters identified as a part of their qualification.
   i. Manufacturing equipment shall be constructed to facilitate routine maintenance.
   ii. Companies shall have in place documented calibration and preventive maintenance programs.
   iii. All calibration and maintenance activities should be documented for qualified equipment.

c. Manufacturing equipment shall be constructed such that contact surfaces do not react with or contaminate the raw materials, in-process materials, or finished products.

d. Documented and verified cleaning procedures shall be in place for equipment and facilities based on risk assessment. Cleaning procedures should be validated to show that they are sufficiently thorough to eliminate the risk of cross contamination, or product carryover from lot to lot of the same product. This validation should be documented.

Best Practices for Design and Maintenance of Facilities and Equipment:

- Where appropriate, warehouse and storage space shall be controlled (temperature and humidity) to comply with stated storage conditions to preserve product integrity.
- Use pictures in operation manuals or procedures for cleaning and maintaining equipment.
- When appropriate, food-grade lubricants and oils should be used.

VI. Assurance of Job Competencies and Training [21CFR211.25, ICH Q7 §3.1]

a. Employees shall have the education, training, and experience or any combination thereof to be considered qualified to perform functions that relate to the manufacture, testing, or distribution of products or services.
   i. Clearly defined and written competencies and job descriptions should be in place for each position directly related to the products and services provided.
   ii. Training should be provided and documented for the required competencies and job descriptions for all employees as necessary.
   iii. Job-related competencies shall be clearly demonstrated and documented for each qualified employee.

b. Employees shall consistently demonstrate competencies in a safe, effective and efficient manner.

c. Periodic training and reviews should be performed to evaluate competencies and job descriptions.

Best Practices for Assurance of Job Competencies and Training:

- A good training program will also include a 'train the trainer' segment.
- All employees shall be qualified before they may perform any activity by themselves.

VII. Adopt Good Hygiene and Housekeeping Practices [21CFR211.28, 211.50, 211.52, 211.56, Q7 §3.2, §4.6, §4.7]

a. A clean workplace and personal hygiene are essential for the preparation of medical products that are free from contamination. As such, procedures shall be in place to maintain the facility in clean and sanitary conditions. These housekeeping procedures should include cleaning schedules, procedures, equipment, and materials to be used.

b. The facility shall include adequate washing and toilet facilities for personal hygiene.
c. Proper clean clothing and personal protective equipment shall be available for each job function directly related to the products and services provided.
d. An appropriate written personal hygiene program shall be in place and practiced by each employee.

Best Practices for Adopting Good Hygiene and Housekeeping:

- Place signs around the facility in key locations to remind employees of proper hygiene techniques.
- Have a health policy in place which will not allow anyone who is sick to enter any production area.
- Have a procedure to teach employees how to properly put on and use protective equipment.

VIII. Establish a Quality Management Program [21CFR211.22, ICH Q7 §2]

Quality management encompasses all activities from the product or service conception to the delivery of products and services including but not limited to sourcing, material inspection, manufacturing, testing, packaging, labeling and distribution. Every step in the product or services lifecycle requires effective controls to assure quality, which must be built directly into products and services via the systemic control of related processes. Risk based quality control and quality assurance programs should be in place for all processes directly related to the delivery of products and services.

a. There shall be a quality unit. The quality unit is authorized to:
    i. Approve or reject all components and products, based on evaluation of production records, test results, or deviations.
    ii. Approve or reject all procedures or specifications affecting the quality of service or product offered.
    iii. Have a robust in-process and finished product testing program to ensure that specifications have been met.
    iv. Have a robust vendor qualification program in place that relies upon vendor site audits and risk-based, periodic testing of material/component specifications.
b. Quality unit processes and procedures shall be in writing and include the following:
    i. Control of Materials [21CFR211.80, ICH Q7 §7]: Check all materials when they enter the facility to ensure they are in accordance with documented vendor qualification requirements, including, at minimum, an identity test and container/packaging integrity. All materials shall be approved prior to

release for manufacturing, or if rejected, they shall be identified and stored separately quarantined to prevent accidental use. Additionally, procedures shall be in place to prevent the use of expired or rejected materials. Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, and distribution to prevent errors.

ii. Control of Processes [21CFR211.100, ICH Q7 §8]]: Ensure that employees consistently perform each task as described in written approved procedures. Exceptions from internal procedures or expected results are recorded and investigated to assess risk and disposition of product. Procedures ensure that cross-contamination is minimized. Appropriate records shall be maintained to document these activities. Where appropriate, key process indicators should be developed to measure the performance of critical processes.

iii. Packaging and Labeling Controls [21CFR211 Subpart G, ICH Q7 §9]: Labeling and packaging operations shall have sufficient controls in place to prevent labeling errors. The labeling used for each production unit, lot, or batch shall be reviewed against an approved, controlled master label and documented.

iv. Holding and Distribution Controls [21CFR211 Subpart H, ICH Q7 §10]: Procedures and suitable conditions shall be established and maintained to ensure that errors, damage, deterioration, contamination, or other adverse effects to product do not occur during storage, handling, and distribution.

v. Change Control / Change Notification [ICH Q7 §13]: All changes to validated processes shall be planned, evaluated, and formally approved prior to implementation to determine the effect of the change on the validated state of the change to consistently meet pre-determined product specifications. There shall be documented procedures in place to identify critical changes that require customer notification prior to implementation and a documented process for notifying the customer.

vi. Control of Nonconforming Product [21CFR211.110, ICH Q7 §14]: Procedures should prevent the release, shipment, reprocessing or other unintended use of nonconforming product.

vii. Testing and Laboratory Controls [21CFR Subpart I, ICH Q7 §11]: Procedures shall be in place that include the collection, handling, control, and retention of component, in-process, and final product samples. Procedures shall be in place that describe the validation or qualification of analytical methods. Instruments used in testing must be calibrated and analysts performing such tests must be qualified. Test results shall be reviewed and approved by the quality unit prior to product release to ensure conformance with test methods and data integrity.

viii. Corrective and Preventive Action (CAPA): Procedures shall be developed that include a formal investigation of deviations and nonconformities that

include identification of corrective actions and preventive actions based on structured root cause analysis method(s). Tracking and trending should be implemented following implementation of the corrective and / or preventive action to determine effectiveness.

ix. Complaints and Recalls [21CFR211.198, Q7 §15: There shall be documented procedures in place to investigate and address all customer complaints. This procedure must include a formal investigation, including conclusions regarding the subject incident, severity, and extent. The procedure should also define those circumstances under which a recall is initiated and when Health Authorities and customers should be notified. Records of all complaints, returns, and investigation results must be retained.

x. Services: Every step in the delivery of a service requires effective controls to ensure the quality of that service and that each employee of the service provider engaged in the provision of the service is properly trained.

Best Practices for Establishing a Quality Management Program:

- Ensure documented procedures are in place for each key quality activity.
- Create a line clearance check list to ensure the line is properly cleared of previous batch prior to use.

IX. Develop a Proper Supplier Management Program [21CFR211 Subpart E, ICH Q7 §7]

a. A documented process shall be in place for the management of material and service providers to ensure the quality of the materials and services provided. Such process should include requirements for the approval and rejection of suppliers. The procedure should include the following:
   i. Criteria for evaluating suppliers.
   ii. Approved supplier lists shall be maintained.
   iii. The supplier quality management program shall be risk based and appropriate for the materials or services provided.
   iv. The supplier management program should include a supplier qualification process. This may include a desk and/or site audit as appropriate to ensure that all significant suppliers have their own supplier management programs and should address whether suppliers need to comply with GMP requirements.

b. Where appropriate based on a risk assessment, quality agreements should be established between suppliers and customers to evidence a mutual understanding of quality expectations and commitments.

c. Risks to the delivery of materials and services must be evaluated. Processes must be in place to address unacceptable risk.
d. Explicit required quality requirements should be listed in a quality agreement for at least a company's critical suppliers.

Best Practices for Developing a Proper Supplier Management Program:

- Use the Rx-360 Supplier Assessment Questionnaire as part of your supplier management process.
- Use a risk-based approach to manage suppliers.
- Require quality agreements from key vendors.
- This includes loss of integrity to materials or services delivered.

X. Audit for Compliance [ICH Q7 §2.4]

a. A written internal audit procedure shall be in place to ensure compliance with the ten (10) principles of GMPs. These principles, intended to complement any existing quality management system, should be periodically reviewed against current regulatory and industry practices.
    i. The audits shall be conducted to assess whether the implemented procedures and processes are being properly followed.
    ii. Each key process related to the delivery of products or services (this includes but is not limited to facilities, equipment, and operational processes) shall be audited based on a risk assessed frequency.
b. There shall be a process in place for handling external audits.

Best Practices to Audit for Compliance:

- Develop a documented program to train employees how to be auditors. This will improve the audits.
- Use an electronic tool like outlook calendar to schedule audits so they will not be missed.
- Develop a risk-based internal audit program.
- Involve management to ensure that deficiencies are resourced.

5. Risk Evaluation

The understanding and application of GMPs is essential not only for manufacturers of regulated medical products but for all suppliers of products or services throughout the supply chain. Without a fundamental understanding of GMP concepts it is almost impossible to produce regulated products that will meet these requirements. Additionally, adherence to the GMP concepts helps ensure that products are safe and effective for the end user.

Efforts should be focused on identifying and analyzing the processes and systems to address unacceptable risk.

It is difficult to control every process related to the manufacture of regulated products under internal control, it is even more complicated and more difficult to ensure compliance of processes, goods and services not directly under a company's control. This is especially true for suppliers that support regulated medical products.

It is important for suppliers into the regulated medical/drug product supply chain to develop a documented risk management program. This risk program should be used to evaluate and mitigate risks that could impact patient safety due to inherently variable processes and to document the variability in manufacturing processes for which controls cannot adequately manage such variability. This program should be applied at the very least to the most critical aspects of the processes that directly impact their customers.

It is important to fully understand and be able to fully explain through documentation and customer meetings what the products and services were designed to do. There are times when there is not an exact product or service designed for the specific requirements of a customer but a close match is found and the customer may attempt to use a product outside its designed use. It is very important in these instances for the supplier to clarify any differences between the designed purpose of the product and or service and the intended use by the customer before it is used. This clarification is important to prevent any future misunderstandings or potential dissatisfaction by the customer, or more importantly, the potential impact on patients.

Quality cannot be added at the end to a product or service. It needs to be designed into the process yielding a product or service at the beginning. It requires proper research, development of processes, and the validation of those processes. The further removed from the customer's immediate supply chain, the more likely it is that these concepts and GMPs are not applied as expected. Therefore, it is important to evaluate the risks along the supply chain as well as the final products or services provided.

Best Practices for Risk Evaluation:

- Integrate risk-based thinking throughout the entire quality management system.
- Utilize tools such as FMEA, HACCP, and FTA to identify and manage risk.

6. Conclusion

Current global supply networks and communication technologies have opened access to seemingly endless varieties of products and services. Selecting suitable products (and services) begins with understanding what impact the products and services have within a manufacturing process from start to finished product release.

Understanding and assessing risk prior to the selection and sourcing of products helps to avoid misunderstandings between the intended use and the actual use by a regulated medical product manufacturer.

While change control and notification, comprehensive supplier quality management and audit programs are common within regulated industries, they are not universal. Expecting a product that "technically fits" to be suitable for use is an assumption often made but is frequently incorrect/inaccurate.

Quality cannot be tested or inspected into a product, therefore products that have been produced under defined and controlled conditions of quality are the products on which the customers require in the medical product industry. The GMPs provide the common language for those conditions of quality that can be understood throughout the supply chain.

Developing a plan to implement the "Principles of GMP" is probably one of the most important things a supplier to the regulated medical industry can do. It will help to clarify key quality topics within the quality management system which should generate improvements that can be measured within the internal audits and complaint programs. The implementation of the "Principles of GMPs" will also more closely align the supplier with their customers which can lead to improved relationships and less observed deficiencies during customer audits, and possibly a reduction in complaints as well.

While there may be an initial increase in work to implement the "Principles of GMPs" the results received will justify the effort.

This guide was conceived with the intention that both Supplier and Customer would benefit. A mutual understanding of the expectations between a Supplier and a Customer, may reduce risks, support compliance and improve quality within manufacturing; key elements to increase patient safety.

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