

QbD Auditing Inc.

The FDA defines "Quality by Design" as a scientific, risk-based, holistic and proactive approach to pharmaceutical development which utilizes deliberate design efforts from product conception through commercialization.

QbD Auditing, Inc. will assist in accomplishing the above by:

Quality:

- Improving the quality of supplier reviews by utilizing our strength of technical knowledge and many years of auditing experience.
- Identifying sources of uncontrolled variability in material and processes.
- Ascertaining technically justified specifications based on desired product performance (efficacy and safety) and consistency.

QbD Auditing, Inc. will assist in accomplishing the above by:

Design:

- Utilizing a thorough understanding of how design elements, along with well-defined product attributes and processes relate to consistent product performance.
- Providing pathways to improve supplier relationships and quality of product and services in the areas of product development through commercialization.
- Ensuring the employment of robust quality systems for compliance beginning with product conception through commercialization.

QbD Auditing, Inc. will assist in accomplishing the above by:

Auditing:

- Providing technical assessment coupled with c'GMP auditing of outsourced services and compliance certification.
- Identifying product and services risks associated with the use of outsourced services.
- Performing technical compliance audits which promote continuous improvements for products and manufacturing processes and desired quality.
- Identifying greatest areas of risk which will lead to the interruption of supply chain and then provide mitigation plans employing solutions and sound pathways for continuation of supply.

QbD staff will incorporate a risk management approach by utilizing their full understanding of how product attributes and processes relate to robust product performance by the implementation of technical audits and use of current industry standards for continuance of excellent compliance.

Utilizing the knowledge and experience of the QbD staff to complete your auditing tasks will lead to increased manufacturing efficiency while reducing costs and waste, which for some products can be as high as 50%! It will ensure consistent information and lessen your burden of too much work on too little staff.

Who We Are:

- QbD is a team of recognized subject-matter experts with over 56 years of major Pharma experience in:
- c'GMP audits and compliance
- Technology Transfer processes
- Process optimization
- Clinical manufacturing through commercial manufacturing
- PAI readiness
- Laboratory testing

Combined We Have:

- Experience completing due diligence for technical assessments
- ISO 9000 certification lead auditor experience for ISO 9000 and c'GMP audits of manufacturing processes
- Served as team leads for PAI Readiness
- Personally completed in excess of 200 audits over a 15-year period

Combined We Have:

- Been instrumental in facilitating both domestic and global company startups mainly in the technical arena, compliance and QA documentation
- Certified Black Belts in Process Excellence and Lean Manufacturing
- References in LinkedIn

Combined We Have:

- Over 56 years of technical expertise in the regulated industries, Biotech, Pharma and Medical Device, with experience in product, process, scale-up, technology transfer, commercialization, preapproval inspection readiness, support and post market technical service with regulatory review for annual reports.

What We Offer:

- Audits of outsourced services and internal assessments
- Quality Systems designed for technical industry audits for compliance which is linked to product and process, documentation trail, SOPs, work instructions, batch records, Gap analysis
- CAPA: How it applies, practically [CAPA: OOS, OOT, Nonconformance, Deviations, Complaints, Calibrations, Link to Change Control, Regulators (observations, recalls), Mitigation of Risk (Risk Management)]

What We Offer:

- Supplier/Vendor/Service provider compliance certification
- Technical Assessment:
 - Of Projects (development feasibility)
 - Clients' level of compliance
 - Available process technologies
 - Startups
- Due diligence audits for acquisitions:
- Audits of small development companies: Offer service to them to strengthen their market position.

Top Five Competencies:

- Over 56 years combined experience in practical, hands on compliance auditing in over 200 audits including international inspections.
- Technical experience with Regulatory Filings, CMC sections with no FDA 483 citations.
- Worked on international projects in the areas of technology transfers, regulatory filings, PAI readiness and inspection support.

Top Five Competencies:

- A thorough review of development projects (including Design Review for Medical Devices).
- Design and implementation of Quality Management Systems including audit and remediation of existing QMS and regulatory findings (Regulatory compliance).

Technical Partners:

- Jim Agalloco – Agalloco Associates
- Ken Muhvich , Ph.D. - Micro-Reliance
- Nagesh Nama – Valimation
- Russ Somma, Ph.D. – SommaTech
- Diane Wood - PD Regulatory Services

Affiliations:

