

Adding Value by Integrating cGMP with an ISO 9000 Quality Management System

By John MacLauchlan



About Impact Analytical

Impact Analytical is a US based contract analytical testing laboratory that provides analytical support for five main sectors: specialty chemicals including polymers and silicon materials, medical devices, pharmaceuticals, bioanalytical and agricultural products. Impact Analytical is known as a problem-solving laboratory and can assist in R&D support, method development and validation, required regulatory testing, stability studies, and competitive analysis. Impact Analytical is ISO 9001:2015 certified, DEA licensed, FDA registered, cGMP and GLP compliant.

Introduction

Everyone who works in the Pharmaceutical industry lives and breathes compliance with Current Good Manufacturing Practices (cGMP) as part of their everyday work practices.



The FDA¹ is beginning to expect companies to also have comprehensive Quality Systems. These are now required under 21 CFR Part 820 for Medical Device Manufacturers, and more recently being discussed as becoming a requirement under 21 CFR Part 58, Good Laboratory Practices.

There can be significant value in integrating an overall Quality Management System (QMS) with compliance to regulations such as 21 CFR

Part 210 and 211. The QMS is a formalized system of the Plan-Do-Check-Act process for continuous improvement. The QMS provides a framework in which supporting systems such as Planning, Purchasing, Information Technology, Corrective and Preventive Actions and Change Management work in concert to ensure all activities related to key process inputs and outputs are focused on timely, successful and increasingly more effective delivery of products that meet all stakeholder requirements.

At Impact Analytical, we have developed an integrated QMS that meets the requirements of regulatory standards such as cGMP and GLP² as they apply to analytical testing laboratories and contains the quality system elements that meet ISO 9000 certification requirements.

By designing and implementing an integrated Quality System, the laboratory has encouraged a culture of quality starting with highly visible management involvement and support, including systems that consistently seek to prevent errors, recognize quality achievements, optimize operations, all ultimately leading to minimal errors in our data and our reports, which we consider to be our final product.

Our systems were designed based initially on conformance with the ISO standards, while ensuring our facility and equipment related processes and standards met the regulatory requirements. In order to ensure compliance to the cGMP/GLP standards, we added a number of supplemental practices and processes. These include a validated document management system which maintains a historical archive of all SOPs, formalized compliance training and records, and secure data archives, as well as back up of all electronic administrative and laboratory data. All instruments are qualified to ensure they are operating as expected. Instruments are routinely calibrated with certified standards, and periodically re-qualified to ensure on-going reliability. We have implemented formal study protocols where needed, and the formal Study Director role. All compliance systems and processes, and cGMP/GLP study data are audited by an independent Quality Assurance Unit to assure compliance to the applicable standards.

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The systems and checks we have in place minimize the chances for errors or system failures. If any errors occur, they are detected and corrected early in the process, as well as triggering investigations into the causes of the errors in order to prevent recurrence. While we ensure compliance with all regulatory, customer and QS certification requirements, the system does allow for flexibility in how to carry out the technical aspects of the studies. Changes to our documented systems and procedures can be proposed by any staff member and implemented subject to management and Quality Assurance (QA) approval.

We expect all personnel to participate in decisions about the most appropriate ways to conduct our studies from technical and data quality perspectives.

Laboratory personnel participate on a revolving basis in Quality System Audits under the guidance of the QA unit, which gives them a broader understanding of the quality system, and how their activities impact the overall success of the company. Performance against quality goals and objectives are integrated into the variable pay portion of our compensation.

We have been audited by regulatory agencies (EPA³ and FDA), ISO 9000 certification auditors and numerous customers. We have been successful in meeting their quality requirements, and we strive to continually improve our systems.

Impact Analytical has performed studies such as method validations, stability studies, as well as material characterizations and dosing confirmation concentrations under GLP. We have performed studies such method validations (under ICH⁴ Guidelines), leachables and extractables, stability studies and product conformance analyses under cGMP.

REFERENCES

1. U.S. Food and Drug Administration
2. Good Laboratory Practice
3. U.S. Environmental Protection Agency
4. International Conference on Harmonization of Technical

Requirements for Registration of Pharmaceuticals for Human Use.

