

Book Review

Laboratory Auditing for Quality and Regulatory Compliance; D. Singer, R. Stefan, and J. van Staden, Taylor & Francis, Boca Rotan, FL, 2005, ISBN: 1574445707. 464 pages

Laboratory Auditing for Quality and Regulatory Compliance is an authoritative book for GMP regulated industries. The wide range of topics discussed included documentation, personnel, and facility; concise definitions and terminology were presented; aims and objectives of the guidances' were clearly defined; and in depth discussion of evaluation parameters were analyzed. As a quality auditor in a Pharmaceutical industry, I evaluate other contractors with many different criteria. The information presented direction on auditing many difference laboratories and explained what the requirements mean. Audit considerations for special testing presented very useful sample questions for an auditor such as myself who audits areas which

are not my scientific discipline. For example, the guidance on equipment validation for microbiological laboratories was very informative. I found the technical requirements for evaluation such as testing or calibration very resourceful. Furthermore, non-technical parameters were demonstrated which included documentation and competency of employees. Overall, the information presented a complete overview from preparation to communication and follow-up.

This book discussed key aspects to every quality audit and is highly recommended to a wide range of audience affected by GMP quality. The discussions provided useful tools to identify strengths and weaknesses for anyone in pursuit of quality improvement or evaluation.

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