

VOLUME 2

DIGITAL TRANSFORMATION AND REGULATORY CONSIDERATIONS FOR BIOPHARMACEUTICAL AND HEALTHCARE MANUFACTURERS

DIGITAL DATA, INSIGHTS,
METRICS AND ANALYTICS



Tim Sandle

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Digital Transformation and Regulatory Considerations for Biopharmaceutical and Healthcare Manufacturers

Volume 2

**Digital Data, Insights,
Metrics and Analytics**

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About the Book

Volume 1 addresses numerous topics including building a digital company, big data analytics, advances in Process Analytical technology electronic batch records, Block Chain, technologies to address counterfeit medicines and many other topics. Volume 2 goes on to spell out how pharmaceutical and healthcare manufacturers have been embracing digital technologies as part of the transformation of their business models and to contextualize the current and future-state advancements in the context of the COVID-19 situation of 2020 – the pandemic that impacted every business around the globe.

Details are offered on the various laboratory functions:

- new model healthcare
- ways to use digital data including root cause investigations
- office technology
- data integrity
- digital data research
- search and handling
- protecting ownership security
- e-learning, virtual inspections and many other relevant topics.

The after-effect of the coronavirus measures has been to shift the boundaries between the healthcare businesses and workforce, including more remote working, and the way that companies need to collate and share data internally, with contractors, and sometimes with competitors. Digitalization of data and the analysis of data using digital tools is the new normal.

The disruption caused by the digital transformation of pharmaceuticals and healthcare is not static; it is evolving, and it will continue to evolve. Across the chapters, these volumes put down a marker for where things are currently, where they are likely to develop, and the challenges that adopters face, in terms of practicalities and in maintaining GMP compliance.



About the Author

Dr. Tim Sandle has over 25 years' experience in microbiological research and biopharmaceutical processing. He is Head of Microbiology and Sterility Assurance at Bio Products Laboratory, UK and a visiting tutor with the School of Pharmacy and Pharmaceutical Sciences, University of Manchester. In addition, Dr. Sandle serves on several national and international committees relating to pharmaceutical microbiology and cleanroom contamination control, including Pharmaceutical Microbiology Interest Group (Pharmig) and PDA technical working groups. He is the author or coauthor of several PDA/DHI texts as well as a contributor to others.



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