MERIT SOLUTIONS | LIFE SCIENCES

21 CFR PART 11, PART 820, AND PART 211:
WHAT YOU NEED TO KNOW

In the rapidly evolving world of digitalization, regulatory compliance is an unavoidable piece of the Life Sciences industry. Merit Solutions for Life Sciences relies on its expertise to deliver streamlined, tailored system functionalities built specifically to ensure it.

Here's a look at three challenges we can help you overcome:

21 CFR Part 11

Specifies the requirements for companies that choose to use computerized systems in their compliance efforts.

What regulatory challenges does Merit Solutions solve for within 21 CFR Part 11?

- Validation
- Audit Trails
- Copies of Records
- Record Retention

21 CFR Part 820

CGMP requirements are set forth in this quality system regulation. It is related to the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.

What regulatory challenges does Merit Solutions solve for within 21 CFR Part 820?

- Document Controls
- Purchasing Controls
- Identification and Traceability
- Production and Process Controls
- Inspection, Measuring and Test Equipment
- Process Validation
- Receiving, in-process, and finished device acceptance
- Acceptance Status
- NCRs
- CAPA
- Device Labeling
- Device History Records
- Complaint Files
- And Others.

21 CFR Part 211

The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals.

What regulatory challenges does Merit Solutions solve for within 21 CFR Part 211?

- Personnel Responsibilities
- Equipment, Cleaning and Maintenance
- Retesting
- Sampling
- Labeling
- Electronic batch records
- Complaints
- Product Recalls
- And Others.

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