

Manufacturing Flow Cytometry Reagents under cGMP

Current Good Manufacturing Practice (cGMP) guidelines are the gold standard to ensure products are manufactured with the same specifications and deliver the same performance over lots and time.

Beckman Coulter Life Sciences manufactures its entire Antibody Portfolio under cGMP in facilities that adhere and are certified to the highest industry standards.

cGMP guidelines apply to all aspects of manufacturing shown below.

Buildings and facilities

- Safe environment (total security for employees)
- Environmental, Health and Security optimization through regular EHS audits
- Temperature, humidity and lighting controlled

Organization and personnel

- Highly qualified personnel (continuously trained, with broad industry expertise)
- Internal and external audits by various agencies
- Daily management (enhanced communication, accelerated decision-making and problem solving)

Raw material control

- Robust raw material quality controls
- Procedures from receipt to material approval
- Traceability
- Selected, qualified suppliers

Equipment

- Optimal for the task (innovative, technologically advanced) and properly maintained
- Regular calibration and qualification (valid, reliable)
- Use only state-of-the-art equipment, enhanced obsolescence management process

Warehousing

- Storage in consistently optimal conditions (temperature, humidity, lighting)
- Transportation by compliant contractors
- Systematic controls at reception of goods

Laboratory

- Certificate of analysis for each batch of product
- Documented procedures
- Reliable equipment and qualified people

Production process and controls

- Approved and maintained procedures and standard protocols to ensure consistency over lots and time
- Quality controls at each process step
- 5S and Lean methods to improve manufacturing productivity
- Consistent product formulation and compliant labelling

Documentation

- All documents reviewed and approved by a cross-functional team of experts (quality, operations, etc.)
- High traceability thanks to continuous filing of records during the manufacturing process and archiving them for 15+ years after product expiration
- Procedures reviewed periodically to ensure latest versions are used