Bioproduction regulatory consulting capabilities

Supporting our customers as they implement bioproduction solutions with compliance as a priority—from the decision stage through validation and routine use

Meeting the needs of bioproduction customers just like you

- You require solutions to address bioproduction challenges that still meet your requirement goals
- We inform you about the features of our products that enable you to align your relevant regulatory guidance
- We support evaluation, implementation, and validation of bioproduction solutions
- We provide guidance on regulatory strategy during implementation and qualification of bioproduction solutions
- We provide consultation to support deviation or nonconformance investigations, including guidance on development of Corrective Action Preventive Action (CAPA)

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Regulatory consulting support: technical services

Our vision is to unleash the value of our comprehensive service offering across the breadth of your workflow

Validation guidance

- Consult on validation, strategy, and approach
- Assist in alignment with current industry guidance documents: International Committee for Harmonisation (ICH), regional pharmacopeias (USP, EP, JP, CP), FDA Guidance for Industry, World Health Organization (WHO)
- Review validation protocols, acceptance criteria, and reports
- Support validations at Customer Experience Centers, potentially with a field application scientist (FAS) as a second or third analyst

Regulatory support

- Consult on regulatory strategy: Prior Approval Supplement (PAS), Type C, Chemistry, Manufacturing, and Controls (CMC) update
- Review briefing documents and presentations
- Accompany you when you meet with regulators
- Organize informational meetings with key regulatory thought leaders

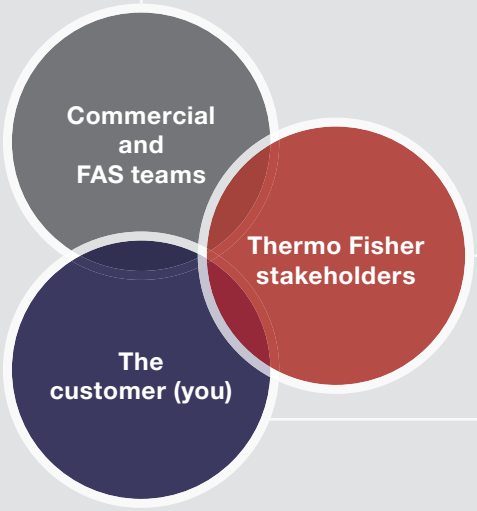
Internal consultation

- Work with internal product development teams to facilitate alignment of product requirements with current regulatory expectations
- Collaborate with the Regulatory Affairs team to channel expectations and requirements between our teams
- Train commercial and FAS teams on regulatory compliance practices
- Assist with Drug Master File (DMF) processes
- Confirm our computer-based systems and software are aligned with regulatory expectations, and assist you with compliance with 21 CFR Part 11, Electronic Records

Industry organizations: active engagement

- Parenteral Drug Association (PDA)
- BioPhorum Operations Group (BPOG)
- Consortium on Adventitious Agent Contamination in Biomanufacturing (CAACB)
- Advanced Virus Detection Technologies Interest Group (AVDTIG)
- NSF Engineering Research Center for Cell Manufacturing Technologies (CMaT)
- National Institute of Standards and Technology (NIST), Standards Coordinating Body (SCB)

Regulatory consulting support: customer engagement



- You will benefit from the value of our regulatory consulting experience through your implementation of the bioproduction portfolio—from evaluation through validation and routine use.
- When you start implementing bioproduction solutions, our support in early development of a qualification and validation plan can help you accelerate the process.

Following review of requirements, we will liaise with relevant stakeholders from Thermo Fisher Scientific and begin development of a support plan. When additional assistance is required, we have a network of consultants that can be engaged.

We will set a meeting with you to review the support plan, identify and engage process owners for both organizations, finalize the plan, and schedule implementation.

Our goal is to help you adopt solutions into your manufacturing processes in an efficient and compliant manner through highlighting our capabilities and establishing regulatory consulting and implementation support from experienced professionals.

Find out more at **thermofisher.com/bioproduction**

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