Applied Biopharm

Applied Biopharm Consulting offers unparalleled expertise in GMP auditing and compliance, Manufacturing Science & Technology (MSAT), Tech Transfer, GMP manufacturing, and Quality Assurance (QA).

We are at the forefront of assisting clients to develop cutting-edge biotherapeutics, encompassing AAV gene therapies, antibodies and fragments, vaccines and recombinant proteins, tailored to meet the dynamic and exacting requirements of the biopharmaceutical industry.

Quality Assurance (QA)

We provide expert guidance on deviation management, investigations and the implementation of Corrective and Preventive Actions (CAPAs). Our consultants have experience in authoring quality records to promptly resolve deviations related to clinical campaigns, Process Performance Qualification (PPQ), or commercial GMP activities. With extensive expertise in biologics drug substance and drug product manufacturing, we offer assistance in change management and process improvements. Services also include implementing site Quality Management (QMS) and Laboratory Information Management Systems (LIMS), covering electronic laboratory notebooks and document management systems.

GMP manufacturing

We support GMP manufacturing operations, assisting with scale-up activities for both single-use and large-scale stainless steel facilities for clinical and commercial production. Additionally, we specialise in facilitating tech transfers into GMP facilities. Our projects include evaluating, selecting, and managing Contract Manufacturing Organizations (CMOs) for biologics and AAV gene therapy programs. Moreover, we conduct on-site assessments and GMP audits of external manufacturing sites as part of due diligence activities for drug substance and drug product manufacturing. We can also offer on-site support, referred to as person-in-plant, to ensure technical and quality oversight during Process Performance Qualification (PPQ) campaigns.

Regulatory CMC

Our team provides regulatory CMC support, including authoring and reviewing the Common Technical Document (CTD) Module 3 (Quality). Team members have extensive experience in preparing and reviewing regulatory submissions, including MAAs and BLAs for European Union and US marketing authorisation applications. Notably, our team members served as regulatory reviewers and co-authors for the first successful biosimilar monoclonal antibody approved for marketing in the European Union in 2013 and have supported expedited fast-track regulatory approval programs.

GMP Inspections and Remediation

Our team has conducted over 80 GMP audits of drug substance and drug product facilities worldwide. Leveraging strategic and technical assessments, we offer prompt identification of areas of non-compliance and assist in mitigating potential risks. Our consultants include IRCA lead GMP auditors and team members who have reported directly to a former District Director of the FDA. Additionally, we have played a key role in long-term remediation projects at manufacturing sites across Europe and Asia. Furthermore, our team has been instrumental in preparing for and coordinating international pre-license and routine GMP inspections, providing assistance with remediation planning and preparing written audit responses to regulatory authorities.

Process Development

With extensive experience in manufacturing process development across various molecules such as monoclonal antibodies, enzymes, PEGylated proteins, vaccines, and AAV gene therapies, we offer comprehensive assistance in upstream and downstream process development. We've established Manufacturing Science & Technology (MSAT) laboratories during facility startups and managed process characterisation and design space studies. We've supported significant industry milestones, including the FDA's approval of the first CAR-T autologous cell therapy in 2017 and the development of the world's first malaria vaccine, recommended for approval by the European Medicines Agency in 2015.

Technical & Operational Leadership

For clients who currently lack the internal leadership dedicated to these core capabilities, seasoned experts with extensive technical or executive leadership experience can step in to provide interim expertise. They support essential operations and organisational capabilities required for successful execution of the company’s strategy, including CMC, process development, tech transfer, QA, QC, and manufacturing.

Selected publications

Newcombe AR. Biopharmaceutical Quality and Compliance: Navigating Good Manufacturing Practice Deviations. Bioprocess International, May 2024

Newcombe AR. Selecting a Contract Manufacturing Organization: Key Considerations for Successful Biomanufacturing. Bioprocess International, 17 October 2023

Hoeksema, *et al*., Advantages of an insect-cell baculovirus expression platform for the large-scale production of recombinant adeno-associated viral vectors. Bioprocess International, 20 April 2023

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Applied Biopharm Consulting Ltd. Cork, Ireland
www.appliedbiopharm.com