Start here…

Avioq, a trusted clinical diagnostics company, has developed a broad line of diagnostics in-vitro assays for the clinical lab. With this experience, we can now offer extensive contract development and manufacturing services. We partner with our clients to develop and advance their individual assay programs. Our R&D scientific team has designed and helped develop numerous medical diagnostic products during the past 25 years.

By applying our staff's experience and a proven quality system, we are able to complete all phases of assay development and shorten timeline challenges that can occur at any stage during product development.

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Quality Systems

Avioq's Design Control and Quality Systems are fully developed. Our facility has been inspected numerous times by FDA and ISO, as well as by external partners. Avioq has met all FDA 21 CFR Part 820 and ISO 13485 requirements for document and purchasing controls, complaint handling, CAPA, non-conformances, design/production/process controls, quality audits, risk management and training.

R&D

Our R&D facility is fully-equipped with modern laboratory spaces. The general laboratory space is divided into dedicated spaces for work in immunology and immunochemistry, microbiology, cell culture, and manufacturing process development performed in our pilot production facility. Our R&D scientific team has designed and developed numerous medical diagnostic products during the past 25 years. As a result, our R&D team, along with our teams in manufacturing, quality assurance and regulatory, have ample experience in all phases of IVD product development, starting from raw material development and finishing with an FDA approved and/or CE marked IVD.

Capabilities

Bio-manufacturing and analytical capabilities include production of antigens produced either in mammalian or bacterial cells, monoclonal antibodies produced in hybridomas, and viral lysates/virus produced from large-scale cell cultures. A variety of tools are used to purify the antigens, monoclonal antibodies or viruses, including gel filtration chromatography, affinity chromatography, tangential flow filtration, and sucrose gradient ultracentrifugation. The facility is fully equipped to perform the conjugation of purified antigens or monoclonal antibodies to a marker, e.g., horseradish peroxidase (HRP), alkaline phosphatase (AP), avidin or biotin. Methods for protein characterization include SDS-PAGE, Western Blot, scanning densitometry, protein concentration determination, and HPLC.

Manufacturing

Our manufacturing facility is FDA (BLA) licensed and ISO 13485 certified. The facility includes a Bio Safety Level 2 facility for large scale virus production, a suite for production of recombinant antigens produced either in mammalian cells or bacterial cells, a multi-room suite for production of kit components, an area for kit assembly, a QC laboratory, several walk-in refrigeration rooms, and warehouse areas for receiving, quarantining and storage of raw materials.

Assay Design and Development

Avioq's research scientists develop assays for our clients based on their requirements. Working side by side Avioq provides efficiencies with shorter timelines to accelerate product development and commercialization.

Our facility is fully equipped to perform the conjugation of purified antigens or monoclonal antibodies to a marker, e.g., horseradish peroxidase (HRP), alkaline phosphatase (AP), avidin or biotin. Methods for protein characterization include SDS-PAGE, Western Blot, scanning densitometry, protein concentration determination, FPLC and HPLC. Avioq has proven processes with the successful commercialization of our own portfolio of in-vitro diagnostics kits.

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Avioq applies our scientific, manufacturing and quality expertise to provide start-up companies or research institutions with immediate services and capabilities to take your assay/test to the next level of use and/or commercialization.

Design and Development Phases

PHASE 0

Feasibility

- Perform research and feasibility studies/activities
- Explore user needs
- Define competitive advantages

PHASE 1

Definition

- Design and development project initiative
- Clearly define product and customer needs
- Verify the accuracy of estimates made and identified in research and concept stage
- Plan for development

PHASE 2

Development and Verification

- Design the product
- Show feasibility of manufacturing at acceptable cost
- Objective demonstration of product requirements to meet customer needs / requirements for intended use
- Design verification

PHASE 3

Industrialization and Validation

- Demonstrate manufacturing reproducibility at acceptable cost
- Fitness for intended use
- Effectiveness and inherent safety (product validation)
- Authorize the initial launch

PHASE 4

Commercialization

- Introduce product to market
- Obtain regulatory approvals according to launch plan
- Monitor product performance in field
- Implement product support
- Initiate market surveillance
- Achieve market acceptance
- Close project and transfer design support to product manager

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