americanBIO

Your Design,
Our Execution

Product Design Transfer Process

4 steps to a successful launch with AmericanBio.

Many companies find the need to outsource manufacturing of a new product or an existing brand. With expertise, experience, and talent in reagent manufacturing, AmericanBio is considered a vital part of customers' operations strategies, becoming a trusted partner to count on. Our New Product Introduction process is well defined and aligned with ISO requirements. This enables us to deliver an equivalent or better designed product seamlessly to our customers. AmericanBio listens to thoroughly understand unique needs, timelines, and strategies to lend the right support where you need it.

Discovery
We learn about your product and operational needs, product life cycle and growth strategy. Together, we assess alignment with AmericanBio strengths.

Design Input
Execute a CDA/NDA. Gain understanding of product definition and specification expectations as well as deliverable expectations.

Feasibility Review
Project review by AmericanBio sales, operations, engineering, and quality staff to ensure your product specification and expectations are well within our capability. Perform Risk Assessment.

Proof of Concept
Development of product prototype prior to scale-up, only if necessary based on Risk Assessment. Receive materials made by you to use as a benchmark.

Proposal Development
Provide a detailed proposal written by our engineers based on the requirements for product design.

Proposal Acceptance & Customer Commitment
Ready to begin execution on the plan described in the proposal. Supply Agreement executed where necessary.

Project Management
We utilize Teamwork Projects software to drive our internal process. It keeps us organized, facilitates communication, and makes us run efficiently.

Documentation Development
Six core documents are provided with your input and approval: Manufacturing Protocol, QC Protocol, Bill of Materials (BOM), Certificate of Analysis (CofA), Safety Data Sheet (SDS), and Labels.

Qualification Plan
Delivery of product based upon your qualification of AmericanBio's manufacturing of your product as described in Proposal.

Validation Plan
A full validation plan can be developed and run with full documentation provided. Quoted separately from the product proposal as the need arises.

Commercial Fulfillment
Full manufacturing run of your saleable product.

Aftermarket Support
Customer Service follow up to learn how the product was received with technical support to address any inquiries, manage documentation or changes through Revision Control.

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Manufacture and Launch your products using our Operational Center of Excellence. We support every facet of customers' reagent manufacturing from product introduction, process improvement, and scalability to supply chain management and logistics.

Our Expertise

Molecular Biology Reagents | Diagnostic & Molecular Diagnostic Solutions | LDT Development | CLIA Requirements

Our Value to You

Speed to Market | Realized Target Revenue | Customer Responsiveness

What you need to get started

Your Design ➤ Expertise from AmericanBio ➤ No Minimum Order Quantities

DEVELOPMENT

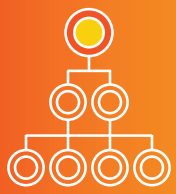
Development Support – Consultation on initial product design and ongoing improvements

Specifications – Define formulations, handling requirements, QC standards & testing requirements for products

Product Presentation – Design customer branded packaging with a wide selection of tubes, vials, bottles, bags, drums, cartridges, kitting or on-board reagents

Validation and Qualification – Stability studies, real time and accelerated testing, component and prototype product testing

Documentation – Create robust documents for manufacturing, QC, and product finishing, all based on your final product specification



MANUFACTURING

ISO Class Operations – ISO 9001:2008 certified, ISO 13485:2003 certified, cGMP compliant

Manufacturing Documents – Full traceability within our document management system

State of the Art Water System – Basis for all quality manufacturing

Raw Material Sourcing – Use AmericanBio qualified suppliers, or yours

Material Grades – ACS, CLIA, Ultra Pure and USP

Handling – Cleanroom or non-classed rooms depending on product requirement

Project Management – We utilize TeamWork software to manage communications and drive your project through our Operations Team

PACKAGING

Filling, Dosing, Capping – Flexibility for specific product use

Labeling – Customer branded with specific design, logo, product & contact information, plus bar coding if needed

Packaging Flexibility – Choose from a wide variety of vials, tubes, plates, bottles, bags, drums, cartridges, and on-board reagent delivery

Finished Product Documents – Supply of documents such as C of A, Instructions for Use, and SDS

SDS Creation – Ability to create Safety Data Sheets in 127 different languages

QUALITY CONTROL

Quality Control – Raw material testing; analytical, functional, in-process, and final product testing

Sample Testing – Lot fulfillment, traceability

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