

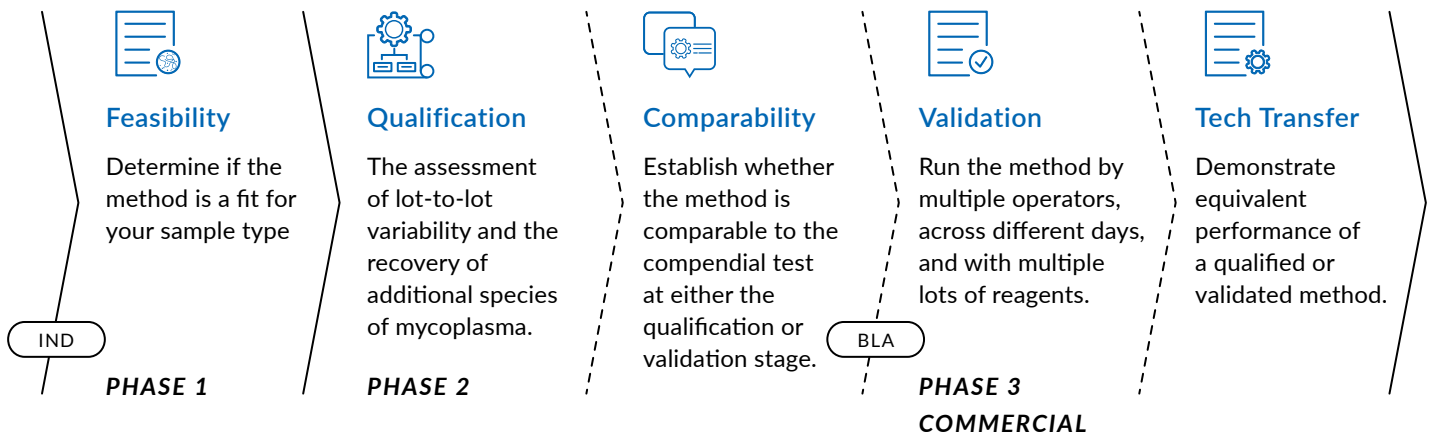


Contract Assay Development, Validation and Transfer Services

While Bionique offers a portfolio of compendial mycoplasma testing, we understand that many novel biologics, cell therapies, gene therapies, and raw materials require rapid molecular-based assays that meet customized product and/or process needs. Bionique brings 30 years of experience developing, validating, and transferring mycoplasma detection assays to empower you with a custom method suited for your unique CMC purposes.

We apply a phase-appropriate approach to the development, validation, and technical transfer of custom alternative methods in accordance with FDA, EMA, JP, and ICH guidelines.

Bionique's Custom Assay Roadmap: Supporting you from IND to BLA







Tap Into Our Diverse Assay Platform Expertise

Bionique is experienced in the latest rapid mycoplasma detection assays. Our GMP-registered site is equipped to develop custom methods across a range of commercially available assay platforms, including BIOFIRE®, MycoSEQ™ and MycoSEQ™ Plus assays. Our project managers work with your scientific team to understand your specific needs, such as intended application, product characteristics, stage of drug development and applicable regulatory requirements. Our comprehensive knowledge and experience with various technologies allow us to deliver a custom assay that is best suited for your lot release testing or in-process monitoring in conformance with current regulatory guidelines.



Assay Development, Validation and Transfer

Our Contract Services

-  **Assay Development and Validation**
We develop, verify, optimize, and validate custom rapid molecular-based mycoplasma assays to meet your requirements in compliance with the specified regulations.
-  **Third Party Validation**
We offer independent, unbiased, third-party validation of next-generation technologies for mycoplasma testing to verify performance, regulatory compliance, and suitability for intended purpose.
-  **Analytical Method Comparability Studies**
We design and conduct studies to demonstrate that the alternative analytical procedure is comparable to the pharmacopoeial prescribed procedure.
-  **Transfer of Assays and Analytical Methods**
We ensure that a custom assay or method that we have developed for you is successfully transferred to you or your CDMO's analytical department.

-  **Stability Studies**
We establish time limits for which biologic materials may be held under specified environmental conditions, thereby informing recommended storage conditions, shelf life, and retesting intervals.
-  **Custom Study Design**
We design custom mycoplasma detection studies that leverage our expertise across raw materials, cell banks, and therapeutic modalities to meet the needs of your novel therapeutic.
-  **Regulatory Consultancy**
We offer regulatory consultation services to assist clients in navigating the complex realm of mycoplasma testing and applicable regulatory requirements to support the development and commercialization of biologics.

Who Benefits From Contract Assay Development Services?



Cell & Gene Therapy Developers

Custom assays are well suited to low-volume and time-sensitive advanced therapies



Biologics Manufacturers and CDMOs

Improve plant turnaround time and gain technical edge over competitors with custom assays



Raw Material & Custom Media Suppliers

Custom assays for short shelf-life media; move inventory more rapidly



PCR Technology Developers

Tap into mycoplasma expertise for your assay in development



bionique.com

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