



## Media by Design Services

Cell culture

# Rapid identity verification testing for bioprocessing materials

Many regulatory agencies are beginning to recommend identity verification testing on each batch of bioprocessing materials to be used in the development and manufacturing of biologic pharmaceuticals.\* However, the complexity of cell culture media and supplements and the confidentiality of formulations can make meeting specificity requirements a challenge when developing an identity confirmation assay.

To help you consistently meet these specifications, Gibco™ Media by Design™ Services now offers a development service for identity verification testing methods. This service is available for any Current Good Manufacturing Practice (CGMP) bioprocessing materials from Thermo Fisher Scientific.

You can rely on our industry experience to help you develop a highly specific, rapid, and compliant identification testing assay specifically suited to your needs.

### Service benefits:

- Offers the simplicity of pass/fail results
- Meets predefined specificity requirements and is compliant with regulatory guidance
- Allows you to easily perform testing in-house, with written test procedures and instrument recommendations provided
- Includes a report of the method development approach, analytical technologies utilized, data, and analysis from the development laboratory work
- Electronic method files may be included, based on instrumentation used
- Includes method transfer and post-development
- Optional quality control validation of the method, with testing on your certificate of analysis (CoA), if required

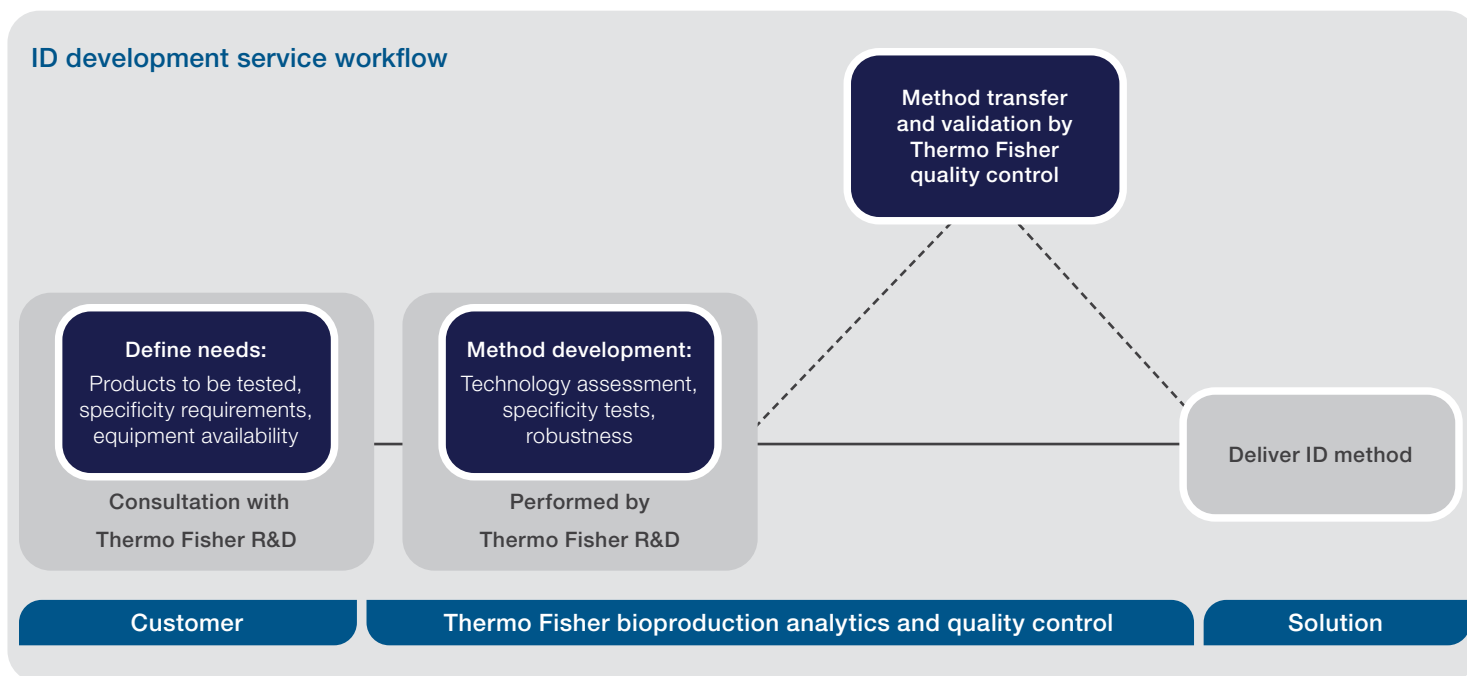
\* US FDA Compliance Guidance Q7 and EMA Guidance ICH Q7, Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

### Technological flexibility

Instrumentation recommended for carrying out the service can be customized to your needs, based on specificity required per each bioprocessing material, your time, and resources available. Some examples of technologies that may be used to perform identity verification testing include basic methods (e.g., osmolarity, pH, conductivity), spectroscopy methods (e.g., FT-IR, Raman, X-ray fluorescence), and quantitative methods (e.g., chromatography, elemental analysis, mass spectrometry).

### Support optimized for your success

Our team's extensive analytical experience and guidance can provide support throughout the process. The following diagram details the steps involved in a typical workflow.



### Contact us today

Let us help to develop an ID verification method test for your bioprocessing products from Thermo Fisher. Learn more today by contacting your field application scientist or technical sales specialist.

Learn more at [thermofisher.com/bioproductionanalytics](https://thermofisher.com/bioproductionanalytics)

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