

Strengthening biopharma workflows with spectroscopy

Biopharmaceuticals – also known as biologics – are medical products that are manufactured, extracted, or synthesized from a biological source. Biologics are structurally and chemically complex, therefore it can be difficult to accurately characterize the processes and products during manufacturing.

This infographic will outline the biopharma manufacturing workflow and explore ways to optimize quality assurance using the latest spectroscopy solutions.

Types of biopharmaceuticals

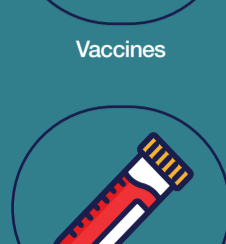
Various biopharmaceuticals exist on the global therapeutics market.



Gene therapy



Growth factor therapy



Vaccines



Monoclonal antibodies



Cell therapy



Protein therapy



Spectroscopy solutions for biopharma workflows

While each are produced using different biological source material, all share common processing requirements including upstream and downstream processing before packaging for delivery to patients.

Upstream

Characterization of raw materials and process reagents

Near-infrared (NIR) spectroscopy	Raw material qualification
Mid-infrared (MIR) spectroscopy	Raw material identification
Photoacoustic infrared (PA-IR) spectroscopy	Identification of chromatography resins
Raman spectroscopy	Identification of cell culture media, buffers and polyatomic salts
X-ray fluorescence (XRF) / X-ray diffraction (XRD)	Identification of ionic salts
UV-Vis spectroscopy	Nucleic acid construct quantification

Cell culture expansion in the bioreactor

NIR spectroscopy	On-line monitoring of glucose, lactic acid and ammonia
Raman spectroscopy	Monitoring of cell culture nutrients and metabolites
UV-Vis spectroscopy	Optical density measurements

Seed-train to generate enough cells to inoculate in the bioreactor



Clarification to remove unwanted material

Virus inactivation

Viral clearance to remove remaining virus particles

Purification and polishing chromatography to remove minute particulate material

NIR spectroscopy	Monitoring protein titers
Raman spectroscopy	Monitoring the protein status (glycosylation, aggregation, degradation)
UV-Vis spectroscopy	Quantifying protein concentration

Fill & Finish

Concentration and diafiltration to remove unwanted material

Raman spectroscopy	Concentration of proteins and excipients
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Sterile filtration

Final formulation (dosage and excipients)

NIR spectroscopy	API verification and content uniformity
MIR spectroscopy	Small molecule purity and contaminant identification
Raman spectroscopy	Concentration of proteins and excipients
UV-Vis spectroscopy	Quantifying protein concentration

Filling vials/syringes with the final formulation

Lot release and environmental control

NIR spectroscopy	Moisture content in finished product and stability studies
MIR spectroscopy	Microparticles (foreign particulate identification), identity testing
Raman spectroscopy	Key COAs multi attribute testing (identity, osmolality and others) microparticles (foreign particulate identification)
UV-Vis spectroscopy	Quantifying protein concentration

Innovative spectroscopy solutions

Spectroscopy can be used at each stage of the biopharma workflow to characterize raw materials, analyze production efficiency, assess contamination, and ensure the quality of final products. Optimizing spectroscopy solutions can therefore enhance the entire workflow.

Antaris™ II FT-NIR Analyzer



Measures the absorption, transmission, and reflection of near infrared wavelengths to determine the chemical composition of a sample. This easy-to-use, customizable system offers both rapid and accurate analysis with high-spectral resolution.

Antaris™ MX FT-NIR Process Analyzer



Measures the absorption, transmission, and reflection of near infrared wavelengths using probes or flow cell in process to determine the chemical composition of a sample. This easy-to-use, customizable system offers real time process control solutions.

Nicolet™ iS50 FTIR Spectrometer



Measures the absorption, reflection and reflection of light across a range of infrared wavelengths to determine the chemical composition of a sample. One-touch simplicity and accessory compatibility makes automating entire workflows easy and flexible.

Nicolet™ iN10 Infrared Microscope



Measures the absorption, transmission and reflection of infrared light to build an image of a sample. Its easy-to-use loading, intelligent experiment setup and fully automated design makes image vivid capture efficient and effortless.

Nicolet™ RaptIR™ FTIR Microscope



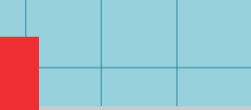
Measures the absorption, transmission and reflection of light across a variety of infrared wavelengths to determine the chemical composition of a sample. Achieve fast results and single micron resolution with intuitive and comfortable-to-use software and automated objective exchange.

DXR3 Raman Microscope



Measures the scattering of laser light using Raman technology, combined with a light microscope designed for the point-and-shoot analysis of sample particles. Achieve fast and reliable results at confocal depth resolution with multiple excitation lasers.

DXR3 SmartRaman Spectrometer



Measures the scattering of laser light using Raman technology to identify chemicals in vials and containers. This non-destructive, non-contact system offers bulk sample capacity and can measure through both clear and colored packaging.

DXR3xi Raman Imaging Microscope



Captures high-resolution chemical and structural images using laser and Raman light scattering technology and instant 3D confocal visualization. Achieve submicron resolution with an easy-to-use adaptable configuration and expanded detector options.

DXR3 Flex Raman Spectrometer



Measures the scattering of laser light using Raman technology to identify the chemical composition of a sample. Additional accessories easily allow micro, bulk and fiber probe based measurements on a compact benchtop footprint.

ARL™ EQUINOX 100 X-ray Diffractometer



Measures the diffraction of an X-ray beam upon a sample. Capture all peaks simultaneously across a wide angular range using high intensity optics and real-time data acquisition without the need for external water cooling.

Evolution™ One/OneC Plus UV-Vis Spectrophotometers



Measures light absorption to identify and quantify a wide range of molecules including liquid and solid state samples. High-resolution data and user friendly Insight Pro software tools to aid regulatory compliance support the development of active pharmaceutical ingredients, quantification of impurities and dissolution testing.

NanoDrop™ One/OneC Microvolume UV-Vis Spectrometer



Measures light absorption to assess the quality and quantity of DNA, RNA or protein within a small liquid volume. Achieve fast and accurate quantification without the need for laborious dilutions, cuvettes or capillaries.

Spectroscopy solutions for every step



Learn more about Thermo Fisher Scientific spectroscopy solutions

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