



Bioprocessing Products

Media components, process chemicals and
parenteral excipients for your bioprocessing needs

spectrum[®]
CHEMICAL MFG CORP
Trusted Since 1971

Built for Quality-Driven Industries

Whether you need nutrients for your formulated media, cGMP chemicals for your downstream purification or multicompendial excipients for your final formulation, Spectrum understands that every process is different. That is why we offer custom, batch-specific packaging, additional testing for specific trace impurities or supply from a certain original manufacturer to support your unique needs. We are able to take a consultative approach with you concerning your projects, small and large.

Spectrum has been providing value added chemical solutions to our customers in the pharmaceutical industry for the past 50 years, and we continue to invest in every facet of our operations to provide current and new customers' solutions for the next 50 years.



In House Laboratory Testing

Our extensive laboratory testing meets the highest standards with the most modern instrumentation in the industry. Spectrum's analytical laboratories are fully equipped with state-of-the-art technology supported by best practices, current Good Laboratory Practice (cGLP) and current Good Manufacturing Practice (cGMP). All of Spectrum's regulated pharmaceutical grade chemicals are tested, processed and warehoused under current cGMP per 21CFR parts 210 and 211 in FDA registered facilities in both New Jersey and California.

Instrumentation

- Atomic Absorption
- Fourier Transform Infrared Spectroscopy
- Fluorescence
- Gas Chromatography
- HPLC/UHPLC
- ICP/MS
- Karl Fischer Titration
- Melting Point
- Potentiometric Measurements (pH and ISE)

Wet Analysis

- Colorimetric Analysis
- Gravimetric Analysis
- Solvent Extraction Techniques
- Titrimetry (Acidimetric, Complexometric and Redox)

Microbiology

- Differentiate Bacterial Colonies
- DNase
- RNase
- Protease
- Endotoxin by LAL
- Total Plate Count
- Yeast and Mold

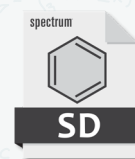
Spectrum offers additional testing and instrumentation, including Proteomic Imaging, Refractive Index, Rotational Viscosity, Specific and Optical Rotation, UV/Vis Spectroscopy, and more. Spectrum can test materials using customer-provided or in-house methods for items not included in the standard compendia. Additional test results can be added to the Certificate of Analysis.

Scientific Documentation

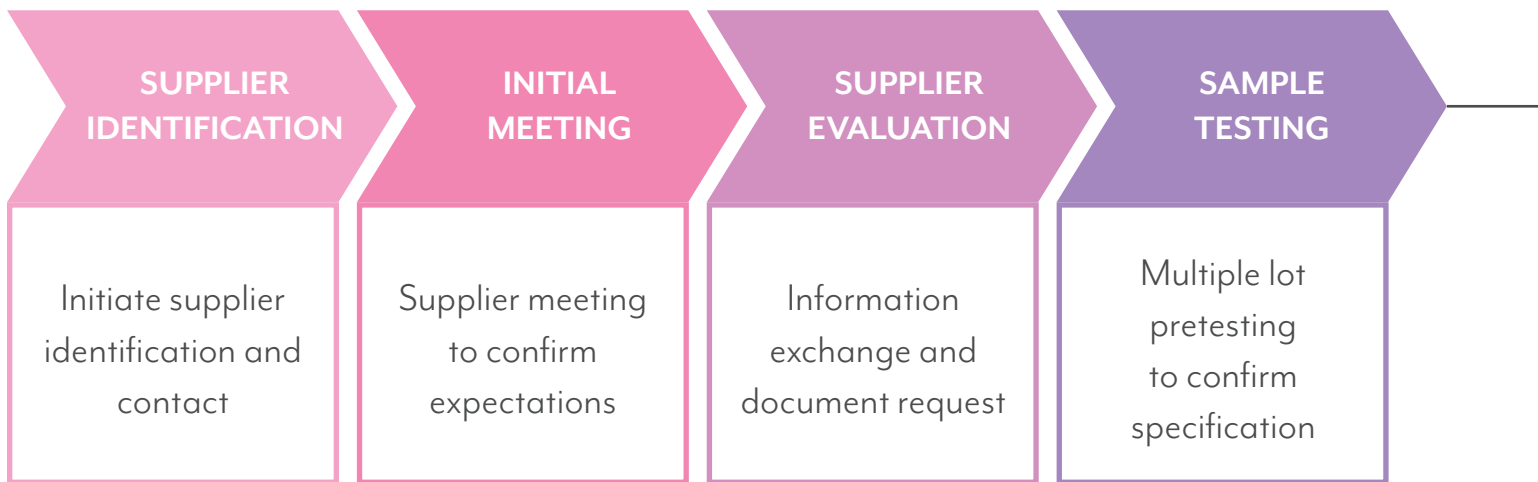
Spectrum's Scientific Documentation program is designed to satisfy your regulatory needs. Statements and certificates in Scientific Documentation dossiers include:

- | | | |
|----------------------------|-------------------------------|--------------------------|
| • Product Specification | • Product BSE/TSE Statement | • General Lot Numbering |
| • Safety Data Sheet | • Product Allergen Statement | System Guidance |
| • Manufacturer | • Product Aflatoxin Statement | • Stability – Shelf Life |
| • Manufacturing Process | • General Label Information – | Guidance |
| Flowchart | Sample Label | |
| • Certification of Quality | • Product Certificate of | |
| Management Systems | Analysis Sample | |

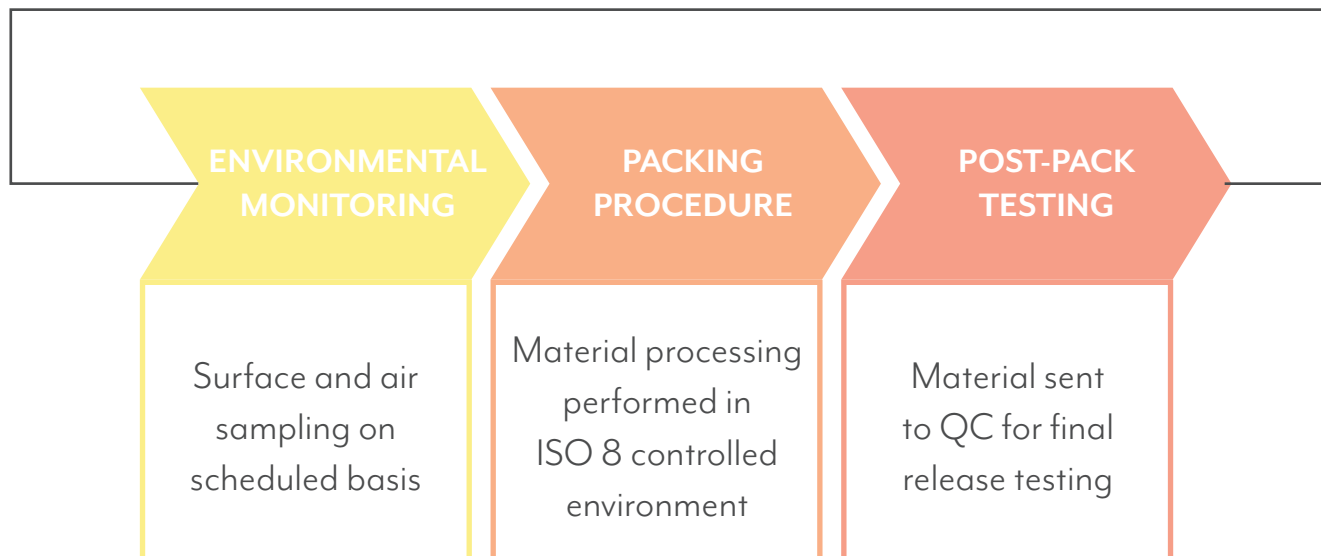
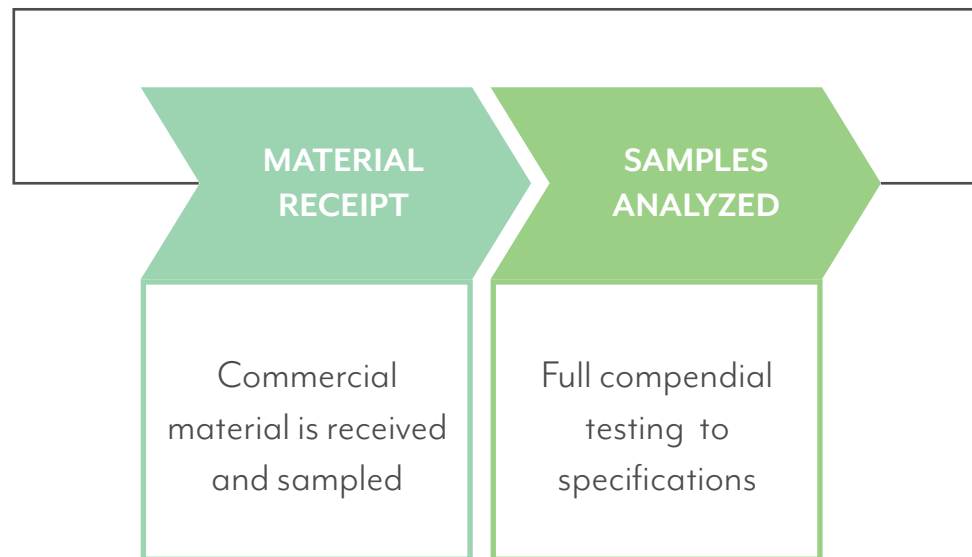
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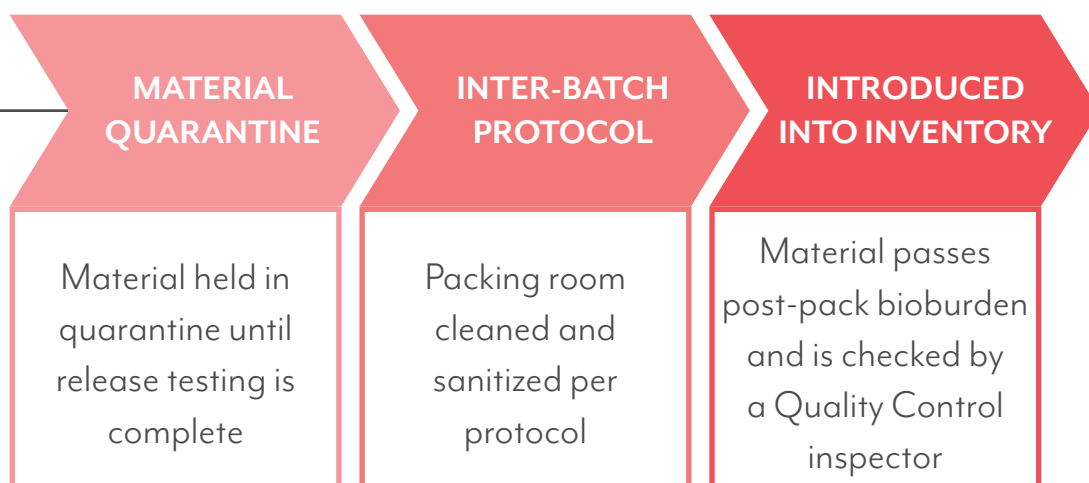
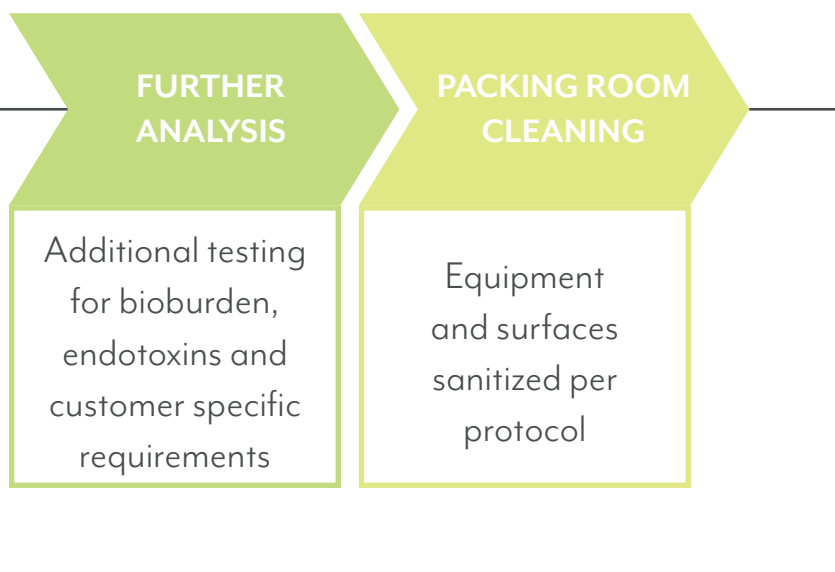
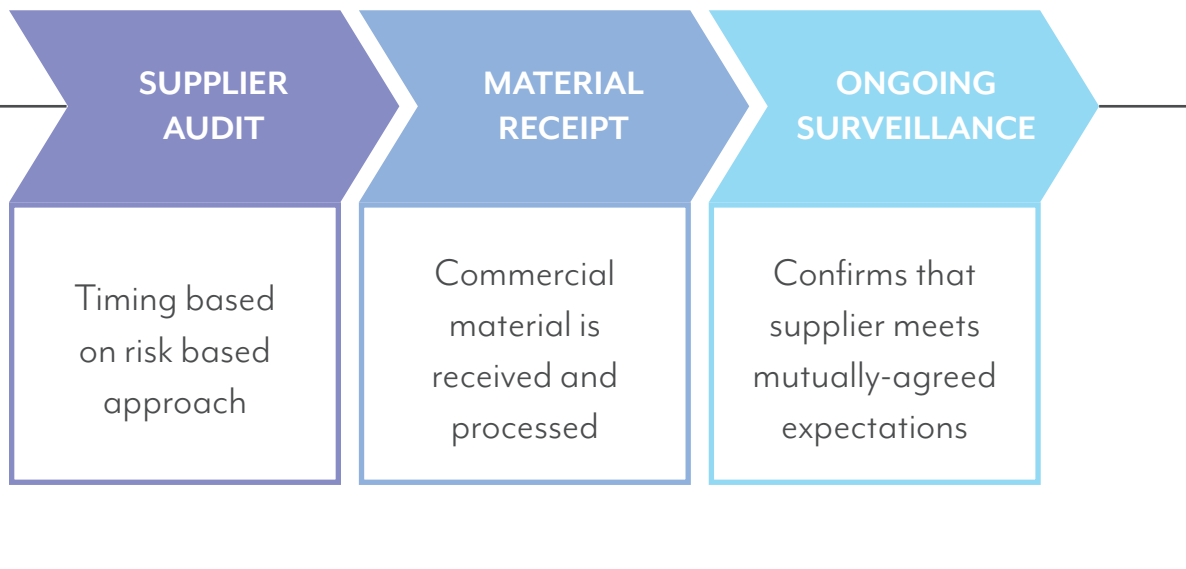


Supplier Validation Process



Material Handling Process

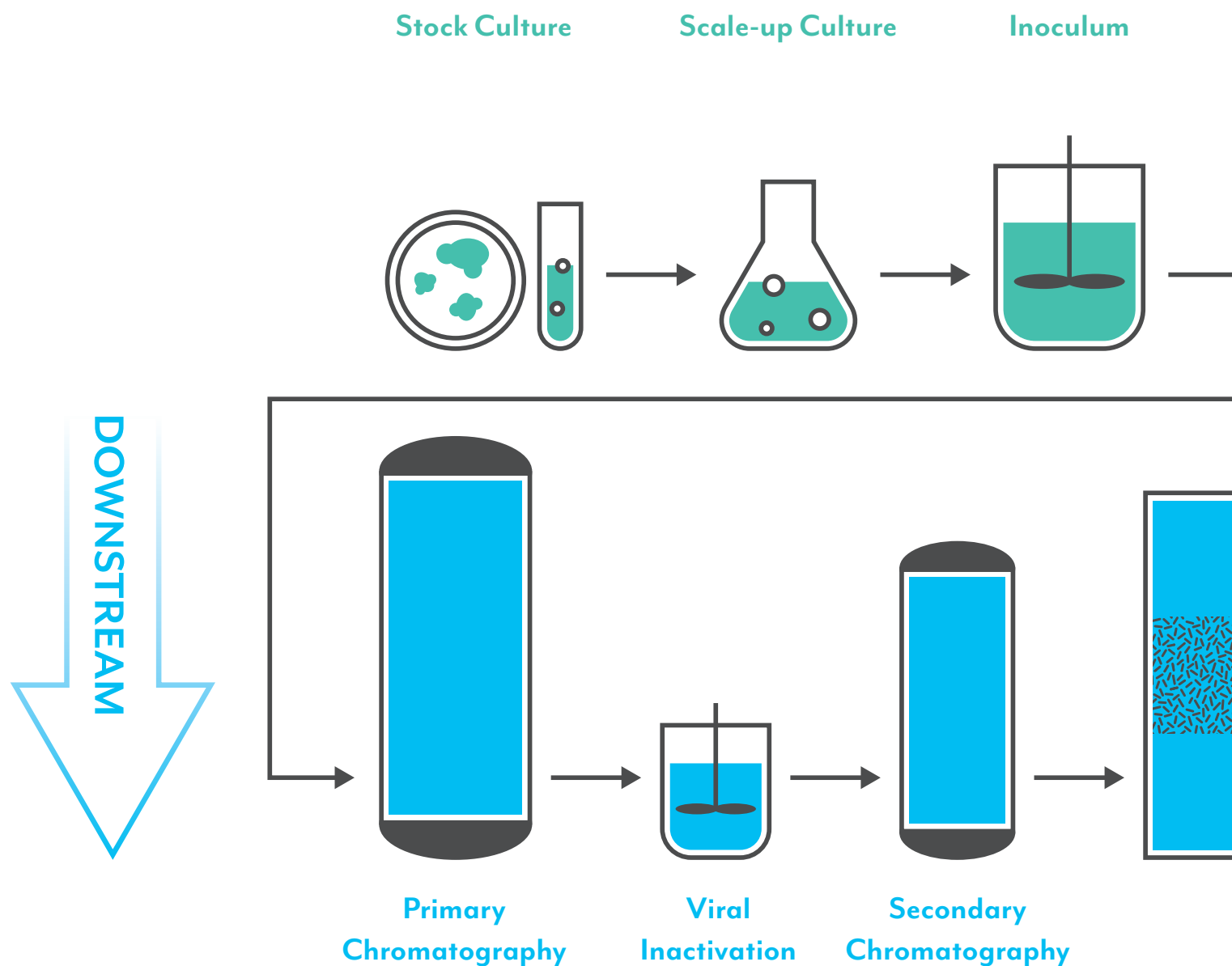




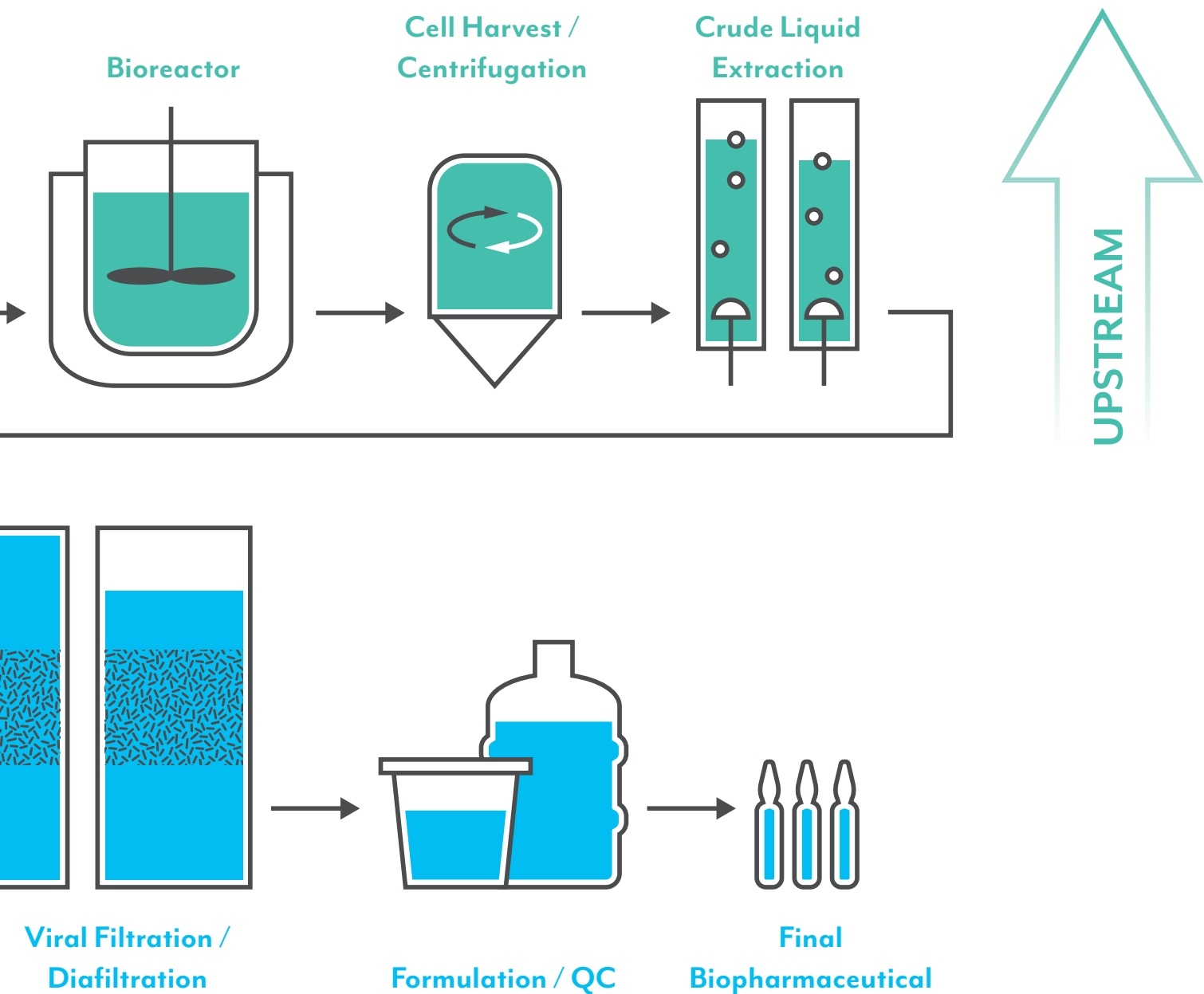
Your Process Needs

Upstream / Downstream

Different phases of your process have different needs, such as chemical type, regulatory oversight and product quantity. Whether you need several hundred grams as an additive to your custom media formulation, metric tons for your downstream purification buffers and salt gradients or several hundred kilograms of a multicompendial excipient to be used in your final



parenteral formulation, our goal is to provide the appropriate product for the specific intended use. We understand that no two customers or processes are identical, and we will work with you to support your unique needs.



The Right Materials from the Start

Being a value-added supplier to the biopharmaceutical and parenteral pharmaceutical markets means starting with the right manufacturing partners. Spectrum supply chain professionals in North America, China and India work with the top manufacturers around the globe, who are committed to working with us. This allows both large and small customers to leverage our sourcing capabilities and contacts in order to receive the best product for specific current and future needs.



Our Product Offering

Upstream / Downstream

Spectrum supplies over 100 unique cell culture additives throughout the world and encourages you to review our current offering for your upstream media needs. Our product offering covers everything from research grade chemicals for upstream R&D and cell culture, through cGMP chemicals for scale-up and production:

- Amino Acids
- Biological Buffers / pH Adjusters
- Inorganic Salts
- Organic Salts
- Sugars
- Vitamins

We recently introduced our unique BioCERTIFIED™ line of biopharmaceutical process chemicals and excipients. This growing program currently includes more than a dozen chemicals, and our intention is to extend the BioCERTIFIED offering to more than one hundred unique chemical products. Doing this right takes time, and we will continue to approach this initiative with the care and security you demand from your suppliers.

In addition to Spectrum's own offerings, we also work with branded suppliers who have the appropriate quality and service to meet biopharmaceutical market demands. Macco Organiques has elected to work with Spectrum in North America, China and select other markets in order to commercialize their high quality line of parenteral API quality excipients for biopharmaceutical manufacturing. With facilities in Europe and Canada, Macco is widely known by end users and regulatory authorities alike in over 100 countries.

Macco Organiques

Macco offers physically modified mineral salts & customized packaging, including blending, grinding/ crushing, milling and repackaging (upon request). All products are packed in a GMP Q7 certified facility equipped with clean rooms conforming to ISO 8 standards. Macco has a passion for quality and for prevention of contamination throughout all production stages, which is why they were hand-selected by Spectrum to be our manufacturing partner for biopharma and parenteral drug products.

Certifications and Registrations

- GMP ICH Q7
- FSSC 22000
- ISO 9001
- FDA inspected
- CoS/CEP
- US Drug Master File
- Japanese Drug Master File
- ASMF

Quality Standards

- EP (European Pharmacopeia)
- BP (British Pharmacopeia)
- USP (U.S. Pharmacopeia)
- JP (Japanese Pharmacopeia)
- FCC (Food Chemical Codex)
- ACS (American Chemical Society)
- ChP (Chinese Pharmacopeia)



bioCERTIFIED™ Products for Biopharmaceutical Manufacturing

- Biopharm industry standard CFR 210/211 cGMP packaging facilities
- Full testing for every lot: bioburden, endotoxin and elemental impurities
- Supply chain verification
- Temperature controlled warehouse
- Technical Service
- CAPA Programs
- Comprehensive regulatory & scientific documentation
- Change control & batch traceability
- 4 Analytical Testing Labs
- US Locations ISO 9001:2015
- China Laboratory ISO 17025



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