Nelson Labs Pharmaceutical Support & Services

Consulting for Chemistry, Manufacturing, and Controls (CMC) * Quality Assurance * Regulatory Affairs * Compliance Assurance

API Production

- Active Pharmaceutical Ingredient (API) Characterization
- Assay & Related Method Development (MD) & Method Validation (MV)
- Elemental Impurities
- Physiochemical Testing
- Reference Standard Characterization
- Residual Solvents MD & MV
- ▲ API Release
- ▲ Stability Studies
- ■ Microbial Limit

IND Enabling

- Container Closure Integrity Testing (CCIT)
- Container Closure Release
- Formulation Development Support
- Assay & Related MD & MV
- Method Feasibility & Verification for Raw Materials
- Raw Material Release
- ▲ Stability Studies
- ■ Bacterial Endotoxin Testing (BET)
- ■ Microbial ID
- ■ Sterility Testing

Clinical Development

- CCIT
- Cleaning Validation
- Elemental Impurities
- Extractables & Leachables (E&L)
- Impurities & Degradation Product Characterization
- MD & MV
- Method Feasibility & Verification
- Nitrosamine Analysis
- Physical & Chemical Testing
- Residual Solvents
- ▲ Lot-Release Testing
- ▲ Stability Studies
- ■ BET
- ■ Disinfectant Studies
- ■ Filter Validation
- ■ Microbial ID
- ■ Sterility Testing
- ■ Sterilization

Commercial

- Cleaning Validation
- Container Closure Release
- Elemental Impurities
- Impurities & Degradation Products
- Nitrosamine Analysis
- Physical & Chemical Testing
- Raw Material Testing Release
- Residual Solvents
- ▲ API Release & Stability
- ▲ Drug-Product Release & Stability
- ■ BET
- ■ Microbial ID
- ■ Sterility Testing
- ■ Sterilization

Life-Cycle Management

- GAP Analysis for Analytical Methods
- Non-Sterile Formulation Support Liquids
- Remedial Validation
- ▲ Drug Release
- ▲ Stability Studies
- ▲ Terminal & Container Sterilization
- ■ Sterilization

Nelson Labs® A Sotera Health company

Sterigenics® A Sotera Health company

● = Physiochemical Testing ▲ = Physiochemical Testing & Microbiology ■ = Microbiology

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