

# H. LAVAL HARLEY

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## SUMMARY

Principal Scientist with extensive experience in solving Pharmaceutical processing and Medical Device concerns related to manufacturing process and development. Wide background in pharmaceutical operations: with a proven track record in process / technical development, manufacturing, validation, research and development, manufacturing process site to site transfer. Manufacturing Processing changes include: material and equipment interface, raw material concerns, material site to site transfer, equipment modification / replacement and process qualification / validation

## AREA OF EXPERTISE

- Development and Scale up of Sterile Bulk Solutions, Filling and Liquids, Semi-Solid, Ointments and Creams.
- Update CMC section of NDA for Sterile Products
- Validation of sterile bulk Solutions and filling
- Project Management
- 6 Sigma Analysis Process
- Product Launch
- Trouble Shooting & Confirmation
- Installation Qualifications
- Cleaning Validation
- Quality Testing Metrics
- Operation Qualification
- Tablet and capsule manufacturing
- Change Management Process
- Root Cause Problem Solving Analysis
- Product Process Transfers
- Providing Technical Representation for FDA Inspections
- Sterile filling and lyophilization

## PROFESSIONAL EXPERIENCE

**CORDIS CORPORATION (J&J Company), Miami Lakes, FL**

**2005 - 2009**

*Principal Scientist* (2007 - 2009)

Subject Matter Expert "SME" for component materials that resulted in the interaction with functional areas that include: Regulatory Affairs, Production Operations, Sustaining Engineering, Quality Control, Quality Assurance, Legal, Sourcing, Purchasing, Packaging, Sterilization and Suppliers. Supplied expertise that would support the continuity of the manufacturing process and prevent production interruptions. Highlights of 2009 include:

- Led team that qualified Rilsan<sup>®</sup> with Tungsten to prevent production interruption after supplier changed size of compounding extruder- \$14mm/yr cost of goods and services.
- Led Monthly Technical Limited Supply Materials meeting to provide transparency into status of limited supply materials and continued to prevent production interruptions from January through December 2009.
- Conducted four product qualification justification assessments.
- Successfully completed green belt training for 6 sigma.

*Principal Engineer* (2005 - 2007)

Primary participant in executing shelf-life extension project for Cypher in San German, Puerto Rico. Assisted in project planning and provided expertise for projects report documentation. Supported production equipment revalidation by reviewing and approving documentation. Highlights are:

- Nitrogen Flow Measurements in Module 4 Spray Coating Carts prior to flow meters installation.
- Performance Qualification Report (PQ) of the Enhanced Spray Coating and work in process (WIP) Vacuum / Heat Dry Process.

**HOFFMANN-LA ROCHE, Nutley, NJ**

**1970 - 2005**

*Manager Technical Operation "3<sup>rd</sup> Party"* (2000 - 2005)

Project Manager providing technical guidance for technical transfer of all galenical products sold in US. Provided project management for individual products and monitored third party manufacturing operations in support of high quality product development / scale up and technical support and efficient, cost effective Technical Development Operations.

- Successfully passed all third party FDA inspections that resulted in no citations.
- Completed transfers within budget and time line.
- Resolved project yield issue that was caused by defective semi-solid capsule equipment process that resulted in increase of yield by 25%.
- Resolved lyophilization issue for third party manufacturing located in Rochester, Michigan and Welwyn Garden City, United Kingdom.

***Principal Investigator, Pharmaceutical Process and Technical Development*** (1994 - 1999)

Managed scale up of manufacturing processes from development to production size batches and equipment. Coordinated change with required function groups such as Production Operations, Drug Regulatory Affairs, Distribution, Quality Assurance, Marketing, Quality Control, Planning, Purchasing and Packaging.

- Timely completion of scale up to meet product launch schedule.
- Developed and implemented new manufacturing technologies into Manufacturing Factories, for example; Electronic Batch Records.
- Resolved production issues by trouble shooting production problems in Humacao and Manati, Puerto Rico Facilities.

***Senior Engineer, Pharmaceutical Tablets, Liquids Semi-Solids and Capsules*** (1990 - 1994)

Supervised team of two professional and eight operators. Met production schedule as required. Conducted training for changes in manufacturing processes. Demonstrated the manufacturing process was conducted as per Current Good manufacturing Process "cGMP".

- Transferred Packaging line from Montréal, Canada to Nutley, NJ and successfully performed all IQ/OQ and Product Performance Qualification for tablet and capsule line.
- Completed Installation Qualification / Operation Qualification (IQ/OQ) for 100% of installed equipment associated with plan products. Completed IQ/OQ for 98% of installed equipment in Process and Technical Development and 85% of the major installed equipment in TLC production.
- Reduced equipment down time by 20% through training operators to perform routine maintenance on equipment instead for waiting for the mechanic.

**Previous Experience and Selective Highlights (Includes Hoffmann-La Roche)** (1969 - 1990)

***Assistant Manager***, assigned to Pharmaceutical Process and Technical Development (1990)

- Project Managed interface activities for Demadex Product line transfer from Boehringer, Mannheim, Germany to Roche, Nutley. This included financial, legal, drug regulatory affairs, planning, sales and marketing interaction, distribution, production, package development, process development, purchasing, and quality control management requirements for transfer. Product line consisted of Demadex Tablets 5mg, 10mg, 20mg, and 100mg - Demadex ampoules 2 ml and 5 ml.

***Assistant Manager***, Sterile and Liquid Products Production (1980 - 1989)

- Technical representative for Vendor Certification Traveling Team that qualified suppliers in US, Belgium, France, Germany, Spain, Italy and Switzerland.

***Senior Group Leader***, Diagnostic Production (1977 - 1980)

- Responsible for manufacturing process for all drug kit testing and cancer test products, sales total 50mm/yr.

***Senior Scientist***, Diagnostic Process Development (1975 - 1977)

- Developed process and published Red Conner Report which introduced manufacturing change that saved Diagnostic operations \$100,000.

*Scientist*, Diagnostic Research and Development (1972 - 1975)

- Participated in six month development program in Marketing Research Department and Roche Diagnostic Products Sales Territories.

*Assistant Scientist*, Q C Analytical Research (1971 - 1972)

- Successfully completed six alternate material source projects for pharmaceutical active ingredients and excipient materials.

*Analyst*, QC Raw Material, Bulk and Finish Dosage (1970 - 1971)

- Performed various analytical testing required to demonstrate that raw materials were acceptable for use in manufacturing process of pharmaceutical products.

### **EDUCATION**

#### **MBA, Business Management**

Fairleigh Dickinson University, East Rutherford, NJ

#### **Bachelor of Science (BS), Chemistry**

Johnson C. Smith University, Charlotte, NC