

**DOUGLAS PAUL ROOT**  
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## **SUMMARY**

Professional chemist with leadership experience for method validation, material qualification, process audits, product investigations, quality system design, and controlled document programs. Advocate for efficient manufacturing and quality systems to prevent, identify, correct, and resolve product failures and near misses. Demonstrated leadership of cooperative teams for product development and commercialization.

## **EXPERIENCE**

U.S. CENSUS BUREAU 2019-2020  
Recruiting assistant working from the Rochester office (ACO 2580). Recruited field workers and participated in field work during the final months of the decennial census field work (September – October 2020).

AGRICULTURAL UTILIZATION RESEARCH INSTITUTE 2007-2016  
A non-profit research institute for developing new uses for agricultural commodities.

### **Senior Scientist of Biomass and Renewable Product Technologies**

Responsibilities

- New processing methods for commodity products
- Technical support for renewable fuels production
- Leadership of research program

GELSTAT CORPORATION 2004- 2007  
A start-up provider of OTC drug products for migraine, arthritis, sinus congestion and occasional sleeplessness.

### **Chief Scientist**

Responsibilities

- All Quality Systems including vendor audits
- Contract manufacturing audits
- Product development
- Laboratory operations and product testing
- Patent preparation and submission

BOSTON SCIENTIFIC CORPORATION INC. 2003 - 2004  
A worldwide leader in medical devices for minimally invasive surgery. Over 14,000 products and 15,000 employees with headquarters in Natick, MA.

### **Manager Operations Analytical Laboratory - Taxus Project**

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| Responsibilities | <ul style="list-style-type: none"> <li>- Quality Systems for testing of Components, In-Process materials, and coated stents</li> <li>- Management of laboratory staff</li> <li>- Certificate of Analysis testing for Taxus product</li> </ul> |
|------------------|---|

CIMA LABS INC., Eden Prairie, MN

1999 - 2002

An entrepreneurial drug delivery company focused on orally disintegrating tablets. OTC and prescription products in several therapeutic areas developed with support from large pharmaceutical partners. Responsibilities completed in October 2002

**Director, Quality Assurance**

2001 - 2002

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|------------------|---|
| Responsibilities | <ul style="list-style-type: none"> <li>- Management of Quality Assurance staff</li> <li>- Review and Approval of all Validation Documents</li> <li>- Development of Product Specification for new products</li> <li>- Controlled document revision, distribution, and control</li> <li>- Production line audits and corrective actions</li> <li>- Incoming material receipt, sampling, and testing</li> </ul> |
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**Director Quality Control**

1999 - 2001

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|---------------------|---|
| Responsibilities    | <ul style="list-style-type: none"> <li>- Management of Validations and QC Departments</li> <li>- Finished product testing for lot release</li> <li>- Equipment validations and preventative maintenance</li> <li>- Raw material specification and testing</li> </ul>            |
| Selected Highlights | <ul style="list-style-type: none"> <li>- Contributed to two NDAs and one ANDA</li> <li>- Successful FDA Pre-Approval Inspections (3).</li> <li>- Successful European pharmaceutical inspection.</li> <li>- Successful product launch of Zomig<sup>TM</sup> in Japan.</li> </ul> |

CYGNUS INC., Redwood City, CA

1997 - 1999

An R&D company focused on transdermal drug delivery systems and medical devices. Marketed products for smoking cessation and hormone replacement therapy.

**Senior Manager, Laboratory Services**

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|---------------------|---|
| Responsibilities    | <ul style="list-style-type: none"> <li>- Management of Analytical R&amp;D and Quality Control</li> <li>- Analytical method development and validation</li> <li>- In-coming component specification and testing</li> <li>- Finished Product specification and testing</li> <li>- Component and finished product stability studies</li> <li>- In-process testing and cleaning validation</li> <li>- Support of process and equipment validation programs</li> </ul> |
| Selected Highlights | <ul style="list-style-type: none"> <li>- Analytical testing for six products including the Evra<sup>TM</sup> transdermal contraceptive system for Johnson &amp; Johnson</li> <li>- Supported formulation development of five products</li> <li>- CM&amp;C sections for three NDAs and two ANDAs</li> </ul>  |

- Established compliance programs for cGMPs and ISO

LAREX INC., St. Paul, MN

1995 - 1997

A start-up company focused on extraction of specialty chemicals from North American trees. Primary product is Arabinogalactan.

**Director, Analytical Chemistry and Technical Services**

Responsibilities

- All analytical and quality control laboratory functions
- Chemical process development for extraction
- Primary regulatory contact for products and facilities
- Supervision of laboratory scientists

Selected Highlights

- Successful construction of a manufacturing facility
- Development and market launch of ten (10) products
- Efficient laboratory systems for product lot evaluation

SHAMAN PHARMACEUTICALS, INC., South San Francisco, CA

1992 – 1995

An early stage pharmaceutical company focused on development of anti-viral, anti-fungal, and anti-diarrheal therapies from traditional herbal materials.

**Director, Chemical Development**

1994 - 1995

Responsibilities

- NMR and MS for lead compound identification
- Primary Extractions of Medicinal Plants
- Development and validation of analytical methods

**Laboratory Director, Chemistry**

1992 - 1994

Responsibilities

- All "Post-Discovery" laboratory programs
- Leadership of a division of twenty-four scientists
- Supervision of six (6) group leaders in Production, Medicinal Chemistry, Formulations, NMR & MS, Pharmacokinetics, and Plant Extractions

**ACADEMIC EXPERIENCE**

UNIVERSITY OF HAWAII AT MANOA, Honolulu, HI

1983 - 1989

**Assistant Professor, Chemistry**

Research in surface electrochemistry. Lecture and laboratory training of undergraduate and graduate students.

**EDUCATION**

Ph.D., Chemistry - Univ. of Arizona    Advisor - G.S. Wilson  
 B.A., Chemistry - Univ. of Minnesota    Advisor - W.E. Noland