

# COLIN D. SMITH

Senior Validation Specialist

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## PROFESSIONAL SUMMARY

An amicable professional able to provide hands-on technical assistance due to an extensive background in parenteral manufacturing as a validation engineer and production team leader. With nearly 30 years of pharmaceutical industry experience, able to prepare and execute installation, operation, and performance validation protocols and summary reports for a wide-range of processes and equipment. Able to quickly apply knowledge of pharmaceutical manufacturing processes and equipment to solve difficult or unique problems. Strong writing and interpersonal skills.

## SPECIFIC AREAS OF EXPERTISE

- Autoclave Qualification & Requal
- Temperature Mapping: Autoclaves, Lyophilizers, and stability/sample retention equipment
- Requalification of EtO and Gamma radiation facilities
- Calibration Programs
- Vial & Equipment Washers
- Data-trace Probes
- Sterile Liquid Filling and Packaging Equipment, Vision systems
- Class M5.5 cleanroom Manufacturing
- Dry Heat Ovens & Depyrogenation Tunnels
- Component Processing: Stopper Washers, Vial Washers (batch and continuous)
- Cleaning Validation: Equipment and Facilities
- Computer/Software Validation
- Terminal & VHP Sterilization
- FDA Consent Decree/483 Remediation
- HVAC Qualification: Shortridge Air Data Multimeter: Pressure differentials, air velocity testing, HEPA filter, room and supply air

## SUMMARY OF QUALIFICATIONS

- ◆ Executed IQ, OQ, and PQs and wrote SOPs for autoclaves at a sterile fill & lyo facility (Class M5.5).
- ◆ Programmed and operated KAYE Digi™ III, Digi™ IV, and Validator 2000™ for temperature mapping studies of Autoclaves, Lyophilizers, Environmental Control Rooms, Refrigerators, Incubators, etc.
- ◆ Responsible for periodic revalidation of existing facility, systems, equipment, and processes, and validation of new equipment and processes.
- ◆ Conducted final & intermediate product inspections, performed line clearances, and completed batch folder reviews.
- ◆ Aseptic Core Committee Member, Parenteral Manufacturing (Class M6.5 and M5.5 work areas)
- ◆ HEPA filter certification program manager and Validation Department Trainer.
- ◆ Experienced software user of MS Office, WordPerfect Office, KAYE Validator 2000.

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**PROFESSIONAL HISTORY**

<b>ECVS, Inc</b> Tucson, Arizona <ul style="list-style-type: none"><li>Senior Validation Specialist</li></ul>	<b>2007 – Present</b>
<b>Watson Laboratories, Inc.</b> Phoenix, Arizona Parenteral Manufacturing Facility <ul style="list-style-type: none"><li>Senior Validation Engineer</li><li>Validation Requalification Coordinator</li><li>Validation Equipment Calibration Coordinator</li></ul>	<b>1992 – 2007</b>
<b>Armour Pharmaceuticals</b> Kankakee, Illinois <ul style="list-style-type: none"><li>Validation Scientist</li><li>Production Supervisor</li></ul>	<b>1978 – 1992</b>  1988 - 1992 1978 - 1988

**EDUCATION**

Bachelor of Arts – Education, University of Wyoming, 1978  
Continuing Education: Computer and Cleaning Validation Seminars (PDA, ISPE, CFPA)

**MEMBERSHIPS & CERTIFICATIONS**

Member, ISPE (International Society of Pharmaceutical Engineers)  
Aseptic (Class M5.5) Gown Qualified