

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 IOQs for process equipment and RO water system for OTC manufacturer.
- ◆ Executed temperature mapping study for OTC batch manufacturing process.
- ◆ 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.

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- ◆ Experienced software user of MS Office, WordPerfect Office, KAYE Validator 2000.

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PROFESSIONAL HISTORY

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