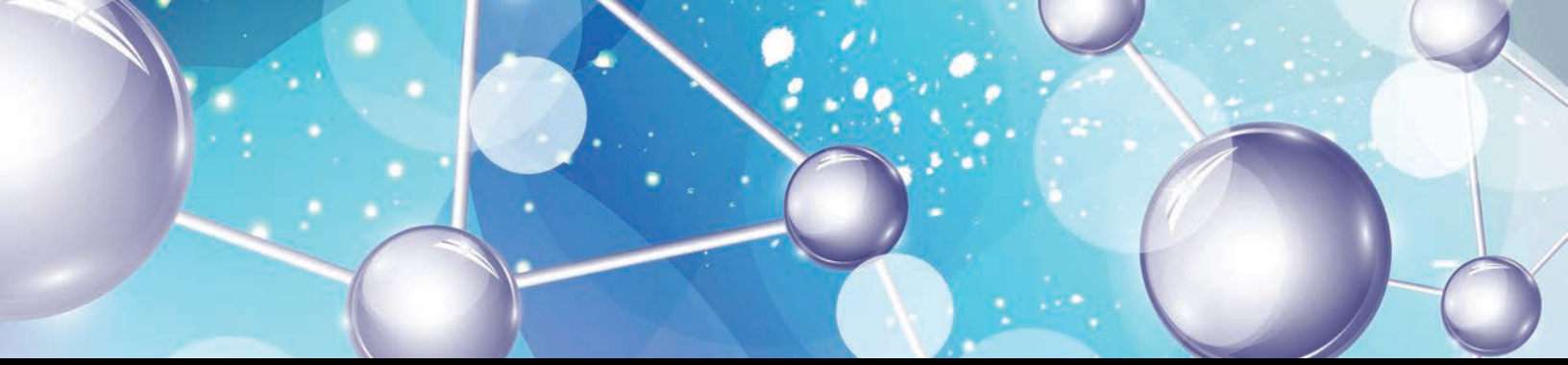


InterProQRA
QUALITY & REGULATORY AFFAIRS

## Need Regulatory Guidance? Get Help From the Source.

**InterProQRA** is a global consulting practice specializing in cGMP and FDA regulatory compliance. We deliver comprehensive solutions to pharmaceutical companies of every size—with FDA veterans recognized for distinguished service leading the way.

**Put FDA-Trained Investigators on Your Projects**

**Guidance from the front lines.** What better way to steer clear of compliance and regulatory problems than to work with former FDA Investigators, those who trained them, and those who helped launch the current inspection program? Who better to help you correct problems than those who managed the inspections and were involved in the warning-letter process and follow-up activities?

InterProQRA puts 30 years of boots-on-the-ground FDA experience to work for you to deliver true insight—wisdom gained from working on the government side of the regulatory table.

**Expertise for Any Regulatory Need**

**Domestic or international.** Our teams have led inspections and were involved in regulatory actions throughout the United States and around the world. Our international experience includes building expertise and developing training programs for firms that manufacture all categories of pharmaceutical dosage forms and APIs for distribution in the US. Around the corner or around the world, we know what's critical for your regulatory success.

## Our Services

### cGMP Compliance Solutions

- Regulatory preparedness/gap analysis
- Auditing; qualification, pre-inspection and due-diligence

### Enforcement Guidance

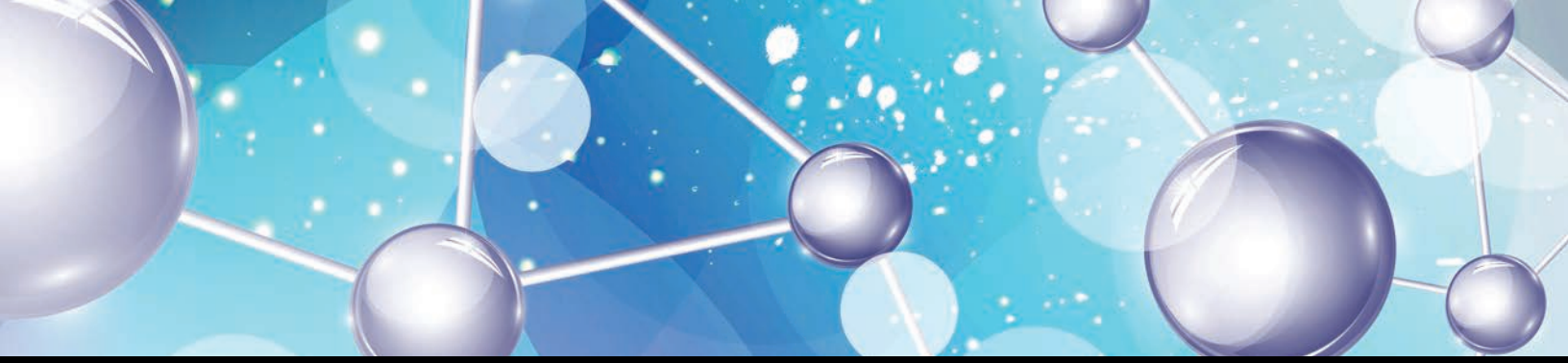
- 483 Response
- Warning Letter
- Consent Decree

### Training

- Annual cGMP
- Aseptic processing
- How to interact with the FDA

### Construction Projects

- Design guidance
- Audits during construction through validation



# Field-Proven Expertise and Results

**From successful submissions to remediation, from site construction to validation, InterProQRA knows how to help you bring your product to market on time and keep it in compliance throughout the life cycle. Contact Brian Burnim at 201.261.7333 or bburnim@interpro-qra.net to learn how we can help you meet your regulatory challenge.**

## Solutions From FDA-Trained Investigators

- **Prepare for facility inspection**
  - Initial or subsequent FDA inspections (active pharmaceutical ingredients and finished dose)
- **Bring facilities into compliance**
  - Support the approval process of NDAs and ANDAs
- **Qualify suppliers and contract manufacturing services**
  - Including laboratories, CMOs, and 3PLs
- **Maintain cGMP compliance**
  - Pre-inspection preparation audits
  - Review Quality Systems for compliance
  - Provide onsite, real-time support during FDA inspections
- **Implement corrective actions and remediations**
  - Prepare responses to FDA Form 483 Observations
  - Prepare remediations and subsequent responses to Warning Letter Charges, including re-inspection assessment and correspondence with the FDA

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