

Intertek Assuris

# Pharmaceutical & Healthcare

Consulting Services



# Your Regulatory Expert

The Pharmaceutical & Healthcare Group within Intertek Assuris has been helping clients develop their products and achieve regulatory approval for over 25 years. Our toxicologists, regulatory affairs specialists, and scientific writers bring years of experience in a variety of product areas:

- Pharmaceuticals (including generics)
- Medical Devices
- Large and Small Molecules
- Biologics & Biotechnology Products (e.g., rDNA proteins, stem cells, gene therapy, biosimilars, and vaccines)
- Combination Products
- Over-the-Counter (OTC) Drugs
- Veterinary Medicines
- Natural Health Products / Dietary Supplements
- Cosmetics and Personal Care Products

**We provide expert advice on multiple aspects of product development programs and assistance with tasks that can arise post-approval.**

We specialize in:

- **Strategic planning** (cost effective development, integration of nonclinical programs with clinical development, and anticipation and resolution of regulatory hurdles).
- **Program management** (including nonclinical safety studies, clinical and CMC advice, and regulatory issues).
- **Regulatory affairs** (regulatory strategies and guidance, preparation of CMC, nonclinical and clinical written summaries and tables, from premeeting packages to filing full submissions for clinical trials or market registration worldwide).
- **Toxicology consulting** (scientific issue resolution, risk and safety assessments, interpretation and positioning of data, scientific writing, liaison with regulatory agencies worldwide, and due diligence activities).

#### Toxicology consulting

Intertek provides expert toxicology consulting services to pharmaceutical, biotechnology, and medical device companies. Intertek's Board-certified experts and their teams offer clients years of scientific research and hands-on industry experience. We deliver innovative and effective solutions that address complex product development, toxicological, and safety issues to our clients worldwide.

#### Regulatory support

Intertek regulatory professionals have detailed knowledge of the applicable legislations and regulations which govern pharmaceutical and medical products, and other regulated or notifiable materials, in North America, Europe, and many other jurisdictions around the world. We continually survey regulatory policies and practices to provide clients with timely information that reflects developments and changes. Our understanding of the intricacies and processes of regulatory agencies is unsurpassed.

The combination helps our clients to develop cost effective and successful regulatory strategies which are 'right the first time'.

#### Scope of services

- Product Development Strategies
- Product Classification in Various Markets
  - Pre-IND/-CTA, INDs, CTAs, IDE, IMPD, BLA, NDAs, NDSs, MAAs, 510(k)s, PMAs, Briefing Documents, Investigator's Brochures, Annual Reports, Integrated Summaries
- Device Establishment Registration
- Post-Marketing Activities (e.g., Label Review)
- Regulatory Strategies and Guidance
- Management of Interactions and Negotiations with Regulatory Agencies
- Chemistry, Manufacturing and Controls (CMC) Regulatory Support and Guidance and Scientific Support Including Cleaning Validation
- Toxicology Consulting
  - Non-clinical Study Design
  - Scientific Program Management
  - Data and Report Review and Interpretation
  - Expert Reports and Literature Reviews
  - GLP Monitoring (Facility and In-Life Audits)
- Risk Analysis and Safety Assessments (Impurities, Extractables & Leachables, Excipients)
- Medical and Scientific Writing
- Assistance with Due Diligence

#### The Intertek advantage

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.



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