



Regulatory Writing & Consulting

Comprehensive regulatory writing & consulting solutions

Pharmaceutical Information Associates (PIA), a division of Thomson Scientific, Inc., is part of the Thomson Regulatory Solutions Group that provides integrated development solutions focusing on:

- Regulatory strategy consulting
- Regulatory writing services
- Data management
- Quality assurance auditing

We can help you to navigate the regulatory hurdles associated with product development and to facilitate approval of submissions by international regulatory authorities. We work with you to achieve the objectives set forth by the International Conference on Harmonisation (ICH) by helping you clearly and effectively present information to support the development and registration of safe and effective therapies.

We offer technical support, specialists and experienced project managers coordinated by team leaders dedicated to your projects. Our commitment to your goals and attention to personalized service provide a time- and cost-effective alternative to meet your objectives.

The members of our team work closely with companies around the world, from multinational pharmaceutical corporations to emerging biotechnology companies.

We save your company time, and work within your budgets, by identifying time and cost-saving opportunities early in the development process. We have participated in the design and preparation of more than 125 submissions, spanning most therapeutic areas.

Our regulatory affairs specialists and writers will work with you on:

- Developing regulatory strategies and identifying submission options
- Designing preclinical and clinical development programs
- Preparing for regulatory authority meetings
- Serving as US agents for non-US sponsors
- Preparing, documenting and maintaining clinical and regulatory Standard Operating Procedures (SOPs)
- Chemistry, manufacturing, and controls documentation and compliance
- Developing protocols, case report forms and consent forms
- Preparing and e-filing all components of Investigational New Drug (IND) applications, including nonclinical and clinical summaries, investigator brochures and updates
- Preparing and e-filing all components of the Common Technical Document (CTD)
- Preparing overviews, study reports and tabulated and written summaries
- Writing clinical study reports and event narratives
- Preparing and filing Abbreviated New Drug Applications (ANDA), 505(b)2, and related submissions
- Database development, data entry, validation and coding, conversion and output
- Quality assurance audits of source documents, regulatory submissions (print and electronic), and site audits.

PIA writers can prepare documents using your in-house templates or our own e-submission tools to facilitate electronic filings.

About Pharmaceutical Information Associates

Since 1990, we have focused on supporting the pharmaceutical development process, from IND to NDA/CTD; our services span drugs, devices, and biologics.

Our Regulatory Affairs Certified (RAC) specialists have extensive experience with submissions to regulatory agencies including the United States Food and Drug Administration (US FDA), the European Agency for the Evaluation of Medicinal Products (EMA), and Health Canada.

To learn more about the regulatory writing and consulting services of PIA, please contact your regional Thomson Scientific office.

Thomson Regulatory Solutions



Critical support and guidance in a shifting regulatory landscape

The Thomson Regulatory Solutions Group provides **technology** to plan and manage your registrations, dossiers and documents, expert **services** to help you compile, design, write and deliver quick, accurate submissions, and the strategic **intelligence** to stay informed on your ever-changing regulatory responsibilities.

Thomson Scientific Regional Head Offices

Americas

101 Gibraltar Road
Suite 200
Horsham, PA 19044
Phone: +1 215 328 4444
E-mail: ts.info.na@thomson.com
Web: www.thomsonregulatorysolutions.com

Europe, Middle East and Africa

14 Great Queen Street
London WC2B 5DF United Kingdom
Phone: +44 20 7344 2800
E-mail: ts.info.emea@thomson.com
Web: www.scientific.thomson.com

Japan

Thomson Corporation K.K.
Palaceside Bldg. 5F
1-1-1 Hitotsubashi, Chiyoda-ku
Tokyo 100-0003 Japan
Phone: +81 3 5218 6500
Free dial: 0800 888 8855
(from Japan only)
E-mail: ts.info.jp@thomson.com
Web: www.thomsonscientific.jp

Asia Pacific

Hitachi Tower
16 Collyer Quay
22nd Floor
Singapore, 049318
Phone: +65 6879 4118
E-mail: ts.info.asia@thomson.com
Web: www.scientific.thomson.com

Other Thomson Scientific Offices around the World

Sydney, Australia
Rio de Janeiro, Brazil
Paris, France
Munich, Germany
Hong Kong
Bangalore, India
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For complete contact information, visit:
www.scientific.thomson.com/contact