Global Regulatory Intelligence on Human Drugs & Biologics — When and Where You Need It

When You Need to
Compare Requirements Across Countries

Excel Spreadsheets: Tarius Cross-Country Tables (CCTs) let you view a wide range of operational details, country by country, to compare, contrast, and better understand how to leverage information across regulatory agencies. For Human Drugs & Biologics, Tarius provides 650 data cells in 5 CCTs across all countries and regions covering:

Clinical Trials/IND Table
- Format, languages and content details of the application;
- Acceptance of Approvals from Other Countries;
- Ethics Committees: timelines, format, languages and content details of the application;
- Pediatric Study Requirements: submission timing and review timeline, content and format;
- Clinical Labeling: regulation references, languages and label contents;
- Registry and Results Reporting, Transparency: Trials requiring reporting, public databases, posting of results, trial termination notification.

Safety Table
- Clinical and postmarket SUSARs/SAEs: Reporting SUSARs/SAEs during clinical trials and for marketed products; including regulation references, format, languages and content of individual reports;
- Periodic Safety Update Reporting Requirements, timetable, data presentation of ADRs, report contents.

Marketing Authorization Application Table
- Format requirements, pathways, electronic gateways, expected review timelines, language, application contents, and more;
- Orphan Designation: Orphan definition, format, languages and details of the application;
- Post-Market Labeling: Regulations, languages and label contents.

Fees Table
- Pre-Approval fees: Clinical Trials, Ethics Committee, Scientific Advice;
- Registrations, market authorizations, variations, etc.: Method, timing and amount of payment.

GMP and GPD Table
- Regulation and guidance, areas covered by legislation such as premises equipment and personnel;
- Complaint Handling: Returns of marketed medicinal products, responsibilities and content, and format of complaint documentation;
- Inspections: Areas, timings and notification of inspections procedures and outcomes;
- Stability Requirements: Climatic zone and stability conditions;
- Good Distribution Practice: Documentation, premises and equipment, storage conditions, supply chains, returns.

When You Need to
Go In-Depth

Local Regulatory Expertise: Use Tarius Expert Summaries to guide you through local submission procedures and practices. More than **20 expert summaries** per country describe the national regulatory setup for human drugs & biologics covering Scientific Advice, Clinical Trials, Marketing Authorisation Applications, Fees, Orphan Drug Designation, Packaging & labelling, Pricing & Reimbursement, Maintenance of Marketing Authorisations, Pharmacovigilance Reporting Procedures, Import and Export, Advertising, Sale to Consumers, and more.
Every expert summary is created exclusively for Tarius by our global network of trusted, independent experts.

When You Need to
Retain and Retrieve Company Data

Local knowledge from your affiliates, distributors and consultants can be difficult to find and keep up to date. **The Tarius Editor** allows you to organize proprietary company data into Cross-Country Tables (CCTs) for easy retrieval! These customizable data sections have full CCT functionality, including active links to documents and websites as well as the ability to export in Excel format.

Using the **Tarius Document Uploader**, you may also upload proprietary company documents in Word or PDF format to Tarius. Users will retrieve the company documents via full-text searching as well as via navigation to company-specific menus. Newly uploaded company documents may be included in the personalized newsletters.

Your company data are stored in a custom secure space, visible only to your colleagues.

When You Need
Global Coverage

Continuously Updated Information: Tarius monitors more than 250 government websites and official journals daily in order to bring you the most up-to-date draft and final versions of relevant acts, regulations, directives, codes, decisions, policy papers, guidelines, warning letters, safety alerts, recalls, press releases, forms, and more. Plus Tarius archives all historic versions for easy retrieval and comparison.
Tarius covers more than 100 countries and regions around the world. Translations of non-English documents enable you to better understand the implications for your company. Tarius provides machine-translated versions at a fixed annual cost.

Tarius includes guidelines, technical reports and policy papers from the following organizations, relevant for human drugs & biologics:
- CIOMS
- EFPIA
- ICH
- OECD
- PIC/S
- WHO

"My Tarius" - Your Personal Dashboard

When You Need to
Share Information with Colleagues

Share documents with ease with your colleagues across the organization. Tarius' web-based interface means every document has a web address, making it easy to bookmark, locate, hyperlink, and share key documents.

When You Need
Company-Specific Research

Get customized regulatory research across the global landscape. Tarius offers project-based research tailored to your specific needs.

Our network of regulatory experts around the world is available to answer specific regulatory questions and/or perform regulatory intelligence and strategy-related activities to help your company make better, more informed decisions.

When You Need to
Stay Up-to-Date

Personalized Newsletters: Sign up to receive a customized newsletter from Tarius featuring only those document categories relevant to your business.

Alerts on Document Changes: Create personalized alerts to receive notifications about new versions and approaching deadlines for submitting comments.

Alerts on Saved Searches: Get notified when new documents are available that match your search queries.

Tarius Administrators may define newsletters and alerts tailored to project needs on behalf of team members.

When You Need to
Find Information Fast

Use "Favorites" to bookmark and quickly retrieve any document. Use "Tags" to organize Tarius documents by project or topic.