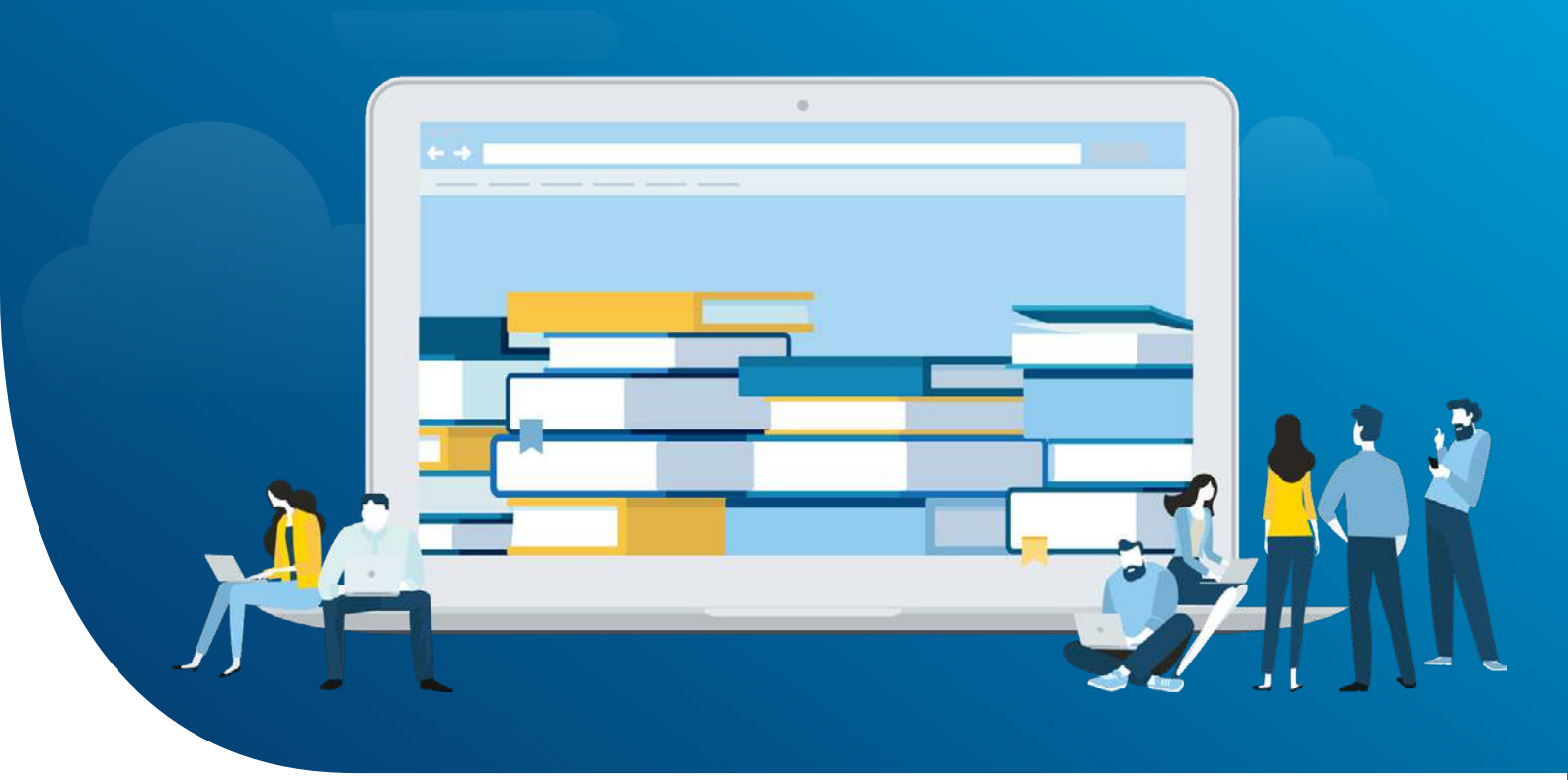
Publishing & Submission of eCTD baselines through the national procedure in Europe



A global specialty-driven biopharmaceutical group focused on innovation and specialty care, entrusted to BlueReg the the preparation and coordinateion of 60 eCTD Baseline submissions for registration in Europe through the National Procedure (NP).

BlueReg
PHARMA CONSULTING

contact@blue-reg.com
www.blue-reg.com

SOPHIA ANTIPOLIS	+ 33 (0)4 22 00 01 00
PARIS	+33 (0)1 82 73 10 00
LONDON	+44 (0)3 333 112 131
AMSTERDAM	+31 (0) 20-799-7487
NEW YORK	+1 (347) 70 81 498
BOSTON	+1 (347) 70 81 498

Challenges

This project consisted of Publishing 60 baseline dossiers in two separates waves for the Client in accordance with the EU eCTD Roadmap and mandatory use of eCTD format for National procedures with the following considerations:

- Project Management and publishing activities
- Tight timelines for dossier preparation and submission
- Process and cost optimisation
- Liaison with Client vs Drug Product Manufacturer, depending on product formulation

BlueReg support

BlueReg assembled a dedicated team of experienced consultants to manage the submission requirements and regulatory publishing to meet the Client's expectations.

I Affiliate Interaction

eCTD Baselines - 1st Wave		eCTD Baselines - 2nd Wave	
Cyprus	Mandatory	Belgium	Recommended
Czech Republic	Highly	Hungary	Recommended
Estonia	Highly	Ireland	Recommended
France	Highly	Italy	Recommended
Greece	Mandatory	Lithuania	Recommended
Italy	Mandatory	Luxembourg	Recommended
Spain	Highly	Poland	Recommended
Sweden	Highly	Portugal	Recommended
		Romania	Recommended
		Slovakia	Recommended
		Slovenia	Recommended
		UK	Recommended

Challenges

II Project Management

- Publishing strategy and client meetings
- Simultaneous multi-country submissions
- Pre and post baseline variations management

III Document Management

- Document Management tracking to facilitate re-use of documents where possible
- Use of Client's EDMS to create master blinders to harmonise dossiers and simplify the process
- Submission tracking

IV Publishing

- Publishing using Client's environment and software
- Quality check and validation of sequences before submission
- Update Regulatory Information Management System
- Upload final submission package for eCTD lifecycle viewing

V Software

- **Extedo eCTDmanager** - to build and publish eCTD baseline submissions
- **Veeva Vault - RIM suite** - to manage submissions, registrations and archive
- **Extedo EURSvalidator** - to ensure eCTD compliance
- **HMA Common European Submission Portal** (CESP to submit applications to regulatory agencies

Achievements

- Successful management and submission of 60 dossiers and handling of concurrent variations
- Tight timelines met for both first and second wave of submissions
- Process optimisation to reduce costs to the Client
- All Client tools and systems maintained and up-to-date
- Client's acknowledgement of BlueReg Publishing expertise
- BlueReg continues to assist the Client with the publishing of baseline submissions for other markets