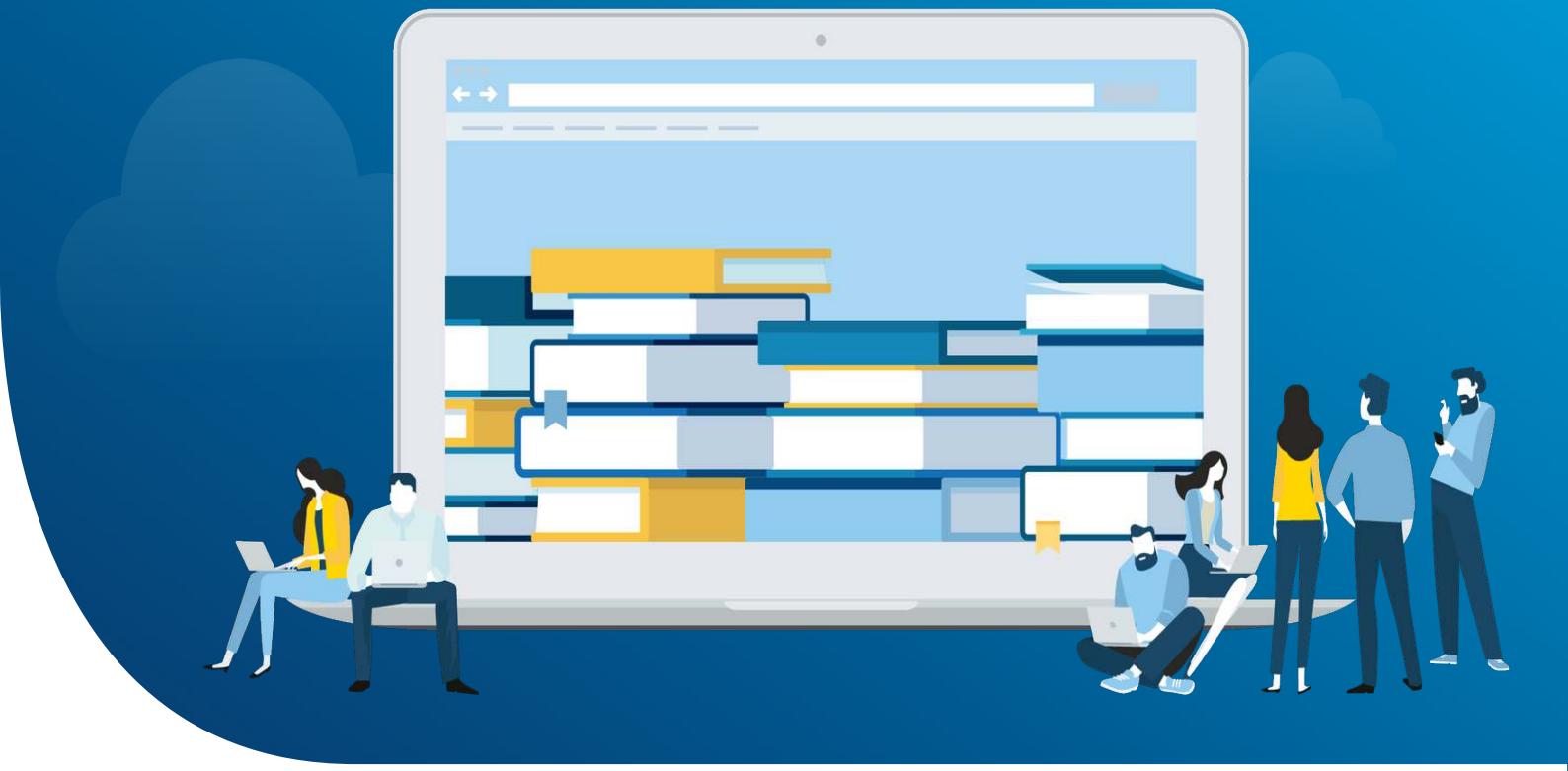
CASE STUDY

PUBLISHING & SUBMISSIONS

Publishing and Submission of a grouped application of Type IA_{IN} Variations (IA-Supergroup)



A global specialty-driven biopharmaceutical group focused on innovation and specialty care entrusted BlueReg to co-ordinate the publishing and submission of a grouped application of Type IA_{IN} variations. This impacted several different products from the same Marketing Authorisation Holder, with different Reference Member States (IA Supergroup). In parallel, to publish and submit the same variation dossiers as a grouped application of Type IA_{IN} variations for nationally registered products.

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

- Working with many departments, product owners, global and local regulatory teams
- Simultaneous Publishing of dossiers in Publishing software
- Managing dossier quality and consistency across all products
- Demanding timelines for dossier preparation and submission

BlueReg support

A project Lead was assigned to assess the team structure and resources required to manage the simultaneous publishing of the dossiers. Several Publishers were assigned to the project and it was critical that dossiers were consistent and that the tight timelines for delivery of each dossier were met.

Team meetings were held to assess the structure of dossiers, set deliverables and factor in any additional steps such as the overall compilation of one single zipped file and time required to upload a large dossier to the submission portal.

1. Project Considerations:

- Use of Client's Electronic Document Management System to co-ordinate submission building, workflow and correct document versioning for publishing
- Publishing using Client's environment and software
- Quality check and validation of sequences
- Compilation of one single zipped package for super-grouping submission
- Compilation of one single zipped package for grouping of nationally registered products
- Submission of dossiers via the Common European Submission Portal (CESP)
- Update Regulatory Information Management System
- Upload final submission packages for eCTD lifecycle viewing

2.Software:

- **Leading eCTD Publishing Software** – to build and publish variations.
- **Regulatory Information Management Suite** - to manage submissions, registrations and archiving
- **Validation Tools** – to ensure eCTD compliance
- **HMA Common European Submission Portal** (CESP) – to submit applications to regulatory agencies.

Achievements

- Successful management and submission of Super-grouping variations and handling of concurrent national variations
- Aggressive submission timelines met
- All Client tools and systems maintained in-line with processes and expectations.
- Client's acknowledgement of BlueReg's project management and publishing expertise
- BlueReg continues to assist the Client with further key publishing projects

How BlueReg can support you ?

Outsourcing Platform on Publishing & Submission Services "OPPUS"

BlueReg is your strategic partner to meet your goals in publishing activities and regulatory submissions worldwide. BlueReg provides a broad range of services for electronic Submissions (eSubmissions). These include publishing expertise (electronic Common Technical Documents (eCTD), non-eCTD electronic Submissions (NeeS) and paper formats), document compliance, gateway submission and project management supported by the expertise of our consultants and our international qualified partners. We provide flexible operational platforms to meet your company's needs for all pharmaceutical forms of drugs and biologicals

- Project Management
- Zone and Agency Expertise
- eSubmission expertise
- Formatting
- Publishing Tools & Expertise
- Document compliance tools & expertise
- Publishing Project Case Study
- Document Compliance Tools & Expertise Study Cases

In all this activities BlueReg will:

- Provide a dedicated team of BlueReg consultants, highly experienced in publishing and submission activities
- Ensure project management oversight to maintain consistency and high quality
- Put in place a robust regulatory intelligence process to ensure compliance with worldwide publishing and regulatory submission requirements

• Be involved at every stage of your projects:
- Formatting your documentation according to electronic submission requirements
- Ensuring publishing according to local needs

• Develop processes and Key Performance Indicators (KPIs) for continuous monitoring

• Propose a quality assurance plan and maintain adequate transition between all project steps

• Publishing and Document Compliance Tools

No matter how complex your requirements are, BlueReg experts can help you to design the appropriate support needed.

For more information please contact us

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

Follow us on social media !

@BlueregGroup

@Bluereg-group

BlueReg
PHARMA CONSULTING