CASE STUDY

PUBLISHING & SUBMISSIONS

System Validation Publishing Software Upgrade

A global pharmaceutical company specialising exclusively in the research, development and marketing of medical solutions for dermatology entrusted BlueReg (BR) to validate its Publishing Software. With the objective to proceed with a major upgrade of their Publishing tool, and the wish to limit the impact on their business, the client contacted BlueReg Publishing Team in order to participate and manage several steps of the validation process.

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Challenges

The Publishing Team had to face multiple challenges:

- Aggressive timelines but operational migration deadline to respect.
- Work with multiple departments;
  - o Client's Publishing Group
  - o IT Functional Support Group (Hardware & Software)
  - o IT Project Management Group
  - o Quality Assurance Units
- Work, collaborate and coordinate activities with the Publishing software vendor.
- Restructuring of Client's organisation.
- Client's limited experience with the Publishing software and the related environment.
- Work from both BlueReg Site and Client's Site

BlueReg support

1. URS/FRS + Review of Risk Analysis Plan:

BlueReg worked closely with IT Quality department in order to identify the features to test during the OQ and PQ phases. In addition, BlueReg also reviewed the Risk Analysis Plan established by the client to confirm the criticality of the selected tests.

2.UAT Tests:

BlueReg first performed a set of informal tests in the development environment in order to anticipate any issues which might occur during the OQ/PQ phase tests. BlueReg worked closely with the IT support unit in order to fix all the connection problems raised during this step.

3.OQ Tests Support for hearing at the HAS:

After an initial step, during which BlueReg helped the client to identify the correct set of tests to perform, we then ran and completed the OQ tests in the validation environment according to the vendor's scripts. We participated in meetings with IT Quality & Operational Teams, IT Support, the Software provider and Publishing department in order to discuss and fix the issues raised at this step. The OQ tests were performed on both BlueReg and the Client's Site.

4.PQ Tests – Writing of the Scripts

Based on our experience with the Publishing Software and Client's processes and environment, BlueReg was asked to write the PQ Scripts.

5.PQ Tests – Running of the Scripts

After writing the corresponding scripts, BlueReg was responsible for performing the PQ tests in the validation environment. As for the OQ tests, we also met with IT Quality & Operational Teams, the Software provider, Publishing department and IT Support in order to discuss and fix the last issues we faced.

6.Quality Documents

As a part of the validation, and in parallel with the operational activities, BlueReg was asked to take charge of writing of the Publishing procedure, describing the process to efficiently use the software and the publishing environment.

Achievements

All the validation steps were performed in due time and validated by the client.

The migration of the Publishing system was performed according to the timelines initially provided by the client.

The BlueReg Publishing Team successfully supported the client during the validation while facing multiple challenging situations (timelines, customer environment, multiple partners, etc.),

The operational migration went smoothly and was performed on time during the booked slot avoiding any impact on the business.

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

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