



Challenges

- › Storage and maintenance of an ever growing number of registration and product data
- › Lowering the Time-to-Market for a product and accelerating the pace in each procedure
- › Fast and easy organization of data and activities
- › Availability of all information for everyone at any time
- › Comprehensive possibilities of generating detailed and summarized reports

Solution and Results

- › Internal organization and synchronization of all data from collaborations with different clients
- › Single point of usage for all employees managing regulatory activities
- › Direct joint use with selected clients that require optimized coordination of products and procedures
- › Separate database sets for each client, so that multiple collaborations are possible



Registration Management



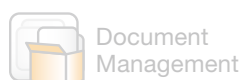
Submission Management



Labeling Management



Pharmacovigilance Management



Document Management



Project Management



Case Study

DRAManager



Regulatory Pharma Net, S.L. (RPN) is an international drug development and regulatory affairs consultancy based in Barcelona and employs 30 professional consultants. RPN offers a full range of services related to drug development plans, clinical and nonclinical strategy, paediatric clinical development, international registration procedures, advanced therapy medicinal products, eCTD/Nees, as well as pharmacovigilance.

Challenge

Handling the increasing client requirements and growing amounts of data and products

Over the last few years RPN experienced dramatic growth in the number of new clients and projects. Today RPN has over 230 clients and oversees 200 active projects. Many of these projects involve international registration procedures. With the main objectives of lowering the Time-to-Market for a product and accelerating the pace in each procedure, RPN faced a large and growing amount of product and registration data that needed to be stored and maintained. In discussions with clients with high numbers of planned or ongoing procedures as well as marketed products, RPN realized the need for a fast and easy way to organize these large amounts of activities and data. All relevant information had to be available for everyone at any time. Users had to be able to filter and extract parts of the data without any difficulty, and to be able to schedule and coordinate the relevant activities during and after authorization of a product.

Being familiar with all the various ways to manage regulatory activities and data, RPN already knew that the most important aspect of a software solution would be an easy-to-use product with an intuitive user interface. A clear visualization of all procedures, products, and respective related activities was a clear must-have, as well as a quick and effective search capability. To realize the main benefit of such a software solution – saving time and money – RPN considered the key criteria for evaluating a software solution to be its capabilities regarding the scheduling of activities, the visualization of project calendars,

the generation of automatic alerts, as well as the ability to generate detail and summary reports. After evaluating a number of project portfolio and registration management solutions, RPN choose EXTEDO DRAManager.

“Our decision for the EXTEDO DRAManager was based on its intuitive user interface, complete set of capabilities, as well as its wide range of customization possibilities. We appreciate EXTEDO’s focus on maintaining compatibility with the ever increasing amount of electronic standards and processes present in regulatory affairs, such as eCTD, pharmacovigilance and labelling.”

(Michael Schaub, Business Development Director of RPN)

Solution and Results

Optimized coordination of internal and external procedures

RPN is utilizing DRAManager to meet two primary objectives: One is the internal organization and synchronization of all data from collaborations with different clients, while the other is its direct joint use with selected clients that require optimized coordination of products and procedures. The tenant-based design of the software allows RPN to have separate database sets for each client, so that multiple collaborations are possible without any issues.

RPN uses DRAManager to reflect the current state of the procedures and products of a client as a basis to plan upcoming maintenance activities, such as PSUR submissions, variations, and renewals.

The synchronization and ease of control of all regulatory data and associated activities will reduce the time and cost spent during product authorization and maintenance. Additionally, the integration with other software necessary for the preparation of eCTDs and electronic reports of pharmacovigilance will be a further step towards global electronic regulatory affairs.

"DRAManager allows us to have a look at the status of all products and registration procedures of a client at any moment. This serves as a single point of reference for all users, and avoids misunderstandings and errors in everyday planning. All crucial and important activities can be scheduled and centrally monitored, minimizing the time required for coordination."

(Izabela Rejdych, Regulatory Affairs Officer of RPN)

About us

EXTEDO is the key solutions and services provider in the field of eRegulatory Affairs.

The complete EXTEDOsuite is unique in all that it covers:

- Product Registration Planning & Tracking
- Submission Management (eCTD, CTD; NeeS, CADDY, ePRISM, eIndex, eNTA, vNeeS)
- Pharmacovigilance Management (SUSAR, ICSR, PSUR, E2B)
- Label Management (PIM, SPL) and
- Document Management

We provide configurable off-the-shelf products, as well as customized and integrated solutions. EXTEDO also provides EURS is Yours, the validation, review and approval system for the EMA and more than 25 Regulatory Authorities worldwide.

Today we serve more than 700 customers in 57 countries ranging from small companies with less than 25 employees to large multi-national organizations. EXTEDO operates in the following markets for human, veterinary and crop protection:

- Life sciences, including pharmaceutical, biotech and biopharma, generics, homeopathics and medical devices
- Healthcare and public sector

EXTEDO is recognized as the worldwide leader in each of our areas of operation.

Additional EXTEDO products used by RPN



> PcVmanager

PcVmanager is a drug safety management software solution based on the E2B and Med-DRA standards that enables you to classify, create, review, submit, and maintain Pharmacovigilance data and adverse event reports.



> eCTDmanager

EXTEDO's eCTDmanager is an off-the-shelf electronic submission management solution that satisfies many of your wishes for eCTD and non-eCTD submissions, no matter if electronic or in paper.

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