Testimonials

Anonymized Version

Global Pharma – EMA, FDA Submission (1)

We have chosen Exalon as eCTD provider for a global NCE submission project - and would like to express our satisfaction for this well-made choice.

With Exalon we were able to manage an extremely large and complex eCTD submission to the EMEA, the FDA and agencies from other countries in parallel in a very efficient way. With their knowledge about international eCTD requirements and sound experience in eCTD compilation and document preparation (referencing and formatting) they supported us in a competent way through the dossier compilation and publishing process. Especially for the FDA submission, their input was extremely valuable for the internal project discussions.

In summary, we experienced Exalon as a partner being able to manage global eCTD submissions efficiently, timely, with high quality and high personal commitment even under challenging conditions and timelines. Our sincere thanks go to the whole team and we certainly look forward to continuing the good collaboration during the forthcoming lifecycle activities and many other eCTD projects.

Director
Regulatory Product Development

Senior Regulatory Affairs Manager
Regulatory Product Development

Global Pharma – EMA, FDA Submission (2)

Our company is working with Exalon since September 2012. Various applications were made since this time:

- Submission of a NDA in the USA
- Submission of a Marketing Authorisation Application in the EU via a centralized procedure
- Various updates of an IND in the USA and e-CTD updates during the NDA and the centralized procedure
- Numerous post approval life-cycle activities in the USA and the EU

During all these activities, Exalon was a highly competent and reliable partner for us. Besides an absolute adherence to timelines and quick response and turnaround times, they performed a very helpful quality control of all our submissions and gave pro-active input to all technical aspects of the eCTD. All eCTD sequences passed the technical validation of the FDA and the EMA.

In all our submissions, sometimes delivered due to last minute changes very close to the deadline, Exalon has nevertheless managed in a perfect manner an on-time submission and showed a high personal commitment, also on holidays and beyond business hours, and provided pro-active solutions for the incorporation of such changes.

Exalon was always up to date about all modifications and changes to e-CTD requirements and guidelines published by the Health Authorities, and we always knew, when we have done our parts, Exalon will take care of the rest. This included also logistic aspects like sending of electronic media to national Health Authorities in the EU. Also this part was done absolutely reliable. Due to the close co-operation over 1.5 years by now, a very close professional relationship has developed and Exalon became an essential and valuable part of our team.

In summary, Exalon is a customer oriented company and is working with high professional standards. They can always be recommended for high quality publishing tasks and submissions.

Head of Global Regulatory Affairs
Global Pharmaceutical Company

Global Pharma – CA Subsidiary

... would like to thank-you for the outstanding services provided by your company for the preparation submissions in the eCTD format per Health Canada requirements.

Your knowledge of the Health Canada requirements for eCTD format has allowed for smooth and efficient preparation of large submissions. Your very timely communication, dedication and support, even after hours, have contributed significantly to meeting our target timelines. The accommodating and very approachable personalities at Exalon have made collaboration and working on these projects a pleasure. Exalon has been an excellent choice for an off-site electronic submission provider.

Director, Regulatory Affairs
Canadian Affiliate, Global Pharmaceutical Company

Global Pharma – Submission Outsourcing

The experience from the last 2 years showed that this outsourcing model works extremely well and fully justifies the decision taken. With Exalon GmbH we found an excellent partner that with his experience, technology and social competence manages our electronic submission business in a highly professional way. The submissions done so far include but are not limited to EU national, MRP/DCP and CP procedures as well as eCTD submissions in the US. Exalon also effectively manages the provision of paper copies to regulatory authorities or our subsidiaries. In addition, Exalon is involved in in-house submission project planning (e.g. managing submission milestones), document processing & publishing, and eCTD trainings.

Regulatory affairs experienced the collaboration with Exalon as an extremely smooth process where activities go hand in hand. We very much appreciate the open and timely communication during the projects as wells as the short-term availability in case of urgent submission activities or tight timelines. The team is highly experienced and committed, proactively provides guidance and understands our needs and expectations. I can strongly recommend Exalon as partner for electronic submission business and would be happy to confirm the above via direct contact in case of interest.

V.P. International Regulatory Affairs
Global Pharmaceutical Company

Global Pharma – Submission Outsourcing – Remote

Kurz vor Abschluss der Aktivitäten in 2014 möchte ich die Gelegenheit nutzen und mich auf das Herzlichste bei Euch bedanken für Euren unermüdlichen Einsatz bei der Unterstützung der Submissions-Aufgaben unserer <*company*> Gruppe. Mit Eurem Support, Eurem Engagement und Eurer Flexibilität habt ihr entscheidend geholfen, unsere anstehenden Aufgaben erfolgreich zu meistern.

Ich freue mich, mit Euch so ausgesprochen erfahrene und kompetente Spezialisten zur Verfügung zu haben, die immer wieder bereit sind, neue Herausforderungen anzunehmen, an Prozessoptimierungen mitzuarbeiten oder diese sich anzueignen und umzusetzen.

Ferner freue ich mich, dass wir auch im nächsten Jahr unsere sehr gute Zusammenarbeit zwischen <*company*> und Exalon fortsetzen können.

Group Head
Global Submission Management & Planning
Global Pharmaceutical Company

Global Pharma – Module 3 Formatting

… So please allow me to thank you all whole heartedly for your cooperation, patience and hard work for the completion of the dossier. It had been an excellent collaboration. The communications I received from all of you were extremely clear and to the point. It definitely made the tasks more aligned and stream-lined. Just perfect for a project☺!

Senior Manager CMC
Global Pharmaceutical Company

US Company – Submission Outsourcing

I have enjoyed working with you and your team over the past year or so. The submissions you've done for us have been flawless and I always appreciate your input and guidance as to how we should approach our submissions and their structure.

Exalon consistently turns our submissions around on a dime, and it is never a problem if we have to make revisions. You just handle it and get it done.

You really show how an external publisher can be an asset to an organization.
Thank you and I hope I'll have an opportunity to work with you in the future.

Director Regulatory Affairs
Mid-Size US Company

DE Biotech Company

As a smaller Biotech company we contacted Exalon to support us during our Document Management System implementation project. Exalon gave as valuable input during the vendor selection phase and helped us to identify and describe the user requirements in a professional manner. As this process is still ongoing, we will further seek Exalon's viable input and support.

Exalon was also selected as external provider for the publishing of complex clinical study reports. We were impressed by the high quality delivered, the quick compilation times, and the pro-active identification of flaws and inconsistencies contained in the reports.

For both tasks the valuable input and the open and straightforward communication was highly appreciated. We are happy to continue the collaboration with Exalon in the future.

Head of Regulatory Affairs
German Biotech Company

UK Regulatory Affairs Consultancy – Biopharmaceuticals

My organization is a small consultancy, which assists small to medium sized biopharmaceutical companies in developing their products and submitting regulatory documents to global regulatory agencies. We have used Exalon to create and submit eCTD documents for a number of our clients at different stages in the development, and we have been very impressed with the service Exalon provides. We have found the Exalon team extremely helpful, very responsive and flexible in their approach to provision of eCTD services. Their knowledge and expertise is beyond reproach and they have consistently supplied accurate electronic regulatory submissions at a highly competitive price. I have absolutely no hesitation in recommending Exalon and we will certainly be using them as a favored supplier and collaborator in the future.

Principal Consultant
Regulatory Affairs Consultancy

UK Regulatory Affairs Consultancy

We have been working with Exalon on several projects and different clients to expand our capacity in the eCTD compilation part of our regulatory services. Exalon is specialised in electronic submission services and we recommend them as a very competent, reliable and fast reacting business partner that always delivered high quality in time. We truly value the professional and personal service they offer and plan to continue our collaboration in the preparation of eCTD dossiers with them in future.

Managing Director
International Regulatory Affairs Consultancy

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