

GALDERMA R&D: A STREAMLINED ELECTRONIC APPROACH FOR QA AUDITS & CAPA PROCESSES

An AssurX interview with Hervé Leroy, Quality Assurance, Galderma R&D

Q: What were the issues that led Galderma to choose an electronic-based solution?

A: Managing audit reports and follow-up actions were based on paper and it was neither an easy task, nor an efficient one.

Q: What were your goals with a new electronic system?

A: Galderma R&D, Quality Assurance planned to acquire an electronic tool that would enable QA to build the master audit plan, schedule individual audits, record and report findings, get response from audit contacts, allow response delegation, and monitor postaudit actions and other CAPA actions.

Q: Were there any other requirements?

A: Compliance with 21 CFR Part 11, zero-client, and easy integration with our existing e-mail system which is Outlook.

Q: Why did you choose CATSWeb for your overall solution?

A: CATSWeb was selected because it is a very configurable system. It could support our project, and also had the capability to support other issues/actions-based business processes, as well as the capability to support most of our QA activities.

Q: Why did you choose SysGen, Inc., an AssurX partner, to configure CATSWeb for your application?

A: Because CATSWeb required some enhanced configuration that we could not do internally. After only a one day meeting with SysGen, Inc., I was convinced that they had the necessary regulatory, technical and business expertise to help us.

Q: How has this streamlined approach using CATSWeb helped Galderma?

A: Several ways:

- Management has access to the audit information as soon as the audit report is issued. They can immediately manage the audit contact's response, and therefore quickly respond to the situation.
- The Auditor can easily produce an electronic audit report, and follow post audit actions and due dates which are assigned to the Auditee.
- The Auditee can delegate the response to each issue with one click, but can still oversee and endorse the final response.
- QA management can oversee problems resolution and trigger CAPA when audit problems are residual.

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Q: How have the users responded to the system?

A: QA and another department all feel comfortable with the new streamlined approach and the tool, which is very user friendly.

Q: Do you see any other applications that you might be configuring with CATSWeb in the future?

A: I am thinking of implementing a Change Request process with CATSWeb. CATSWeb will also be used to support any workflow based on issues, dispositions and actions.

Q: Now that you've had a chance to see CATSWeb and SysGen, Inc., in action what do you like best about the software and the consultants you've worked with?

A: They listen to you, take time to understand your business, and then propose pragmatic and relevant solutions. That was why we chose them.

Q: Would you recommend CATSWeb and SysGen, Inc. to others?

A: Yes, definitely!

About Galderma

Galderma, created in 1981 as a joint venture between Nestlé and L'Oréal, is a fully integrated specialty pharmaceutical company dedicated exclusively to dermatology. The Company has a presence in 65 countries with over 1000 sales representatives and is committed to improving the health of skin with an extensive line of products that treat a range of dermatological conditions including: acne, rosacea, fungal nail infections, psoriasis & steroid-responsive dermatoses, pigmentary disorders, skin cancers and medical solutions for skin senescence. Galderma's new centre in Sophia Antipolis, France is the largest facility in the world dedicated to Research and Development in dermatology.

Galderma leading brands include Differin®, Rozex®/Metro®, Clobex®, Tri-Luma®, Loceryl® and Cetaphil®. Recently launched products include Pliaglis™, a topical anaesthetic for dermatologic procedures in the United States, Epiduo®, an innovative combination product for the treatment of acne in Europe and Argentina and Dysport®, an injectable neuro-modulator for the correction of wrinkles in Brazil and Argentina. The Company's website is www.galderma.com.

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