



Global Pharma Regulatory,
Quality Services & Software
Company.

Expansion Journey 2018 to 2025

500+
Successful
Quality, cGMP
& GxP Audits

8+
Global Offices

700+
Global
Regulatory
Dossiers

600+
International
Clients

39+
Countries
Serving Clients

300+
Team Size

Global Dossier Filing

DMF, CEP, ASMF, VMF, TPMF, IND, CTA, NDA, ANDA, MAA, 510(k), PMA, BLA, NDS, ANDS, ANADA & NADA

eCTD Publishing & Submission

PDF Processing, Doc Assignment, Validation, Verification, Dispatch, Archival & Life-cycle

Pharma Regulatory Software

NextGen eCTD (Simplify Electronic Submissions), NextGen SPL (Automate Package Insert to XML), NextGen PDF Plugin (Submission-ready PDFs) & NextGen eLN (Digitalization of Lab Operations)

Quality, GMP, GxP Audits

Six System, Mock, Vendor Qualification, Remediation, Warning Letter Lifting & Brown/Green Field projects

Global Labeling & Artwork

Package Insert, Artwork/Mockup, Leaflet, ePIL, USFDA SPL, Health Canada SPM & CCDS

Medical Writing & Toxicology

Clinical/Non-Clinical Overview & Summaries, Risk Management Plan (RMP), Environmental Risk Assessment (ERA) & PDE/ADE, OEL & OEB Toxicology Reports



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Leadership/Scientific Team



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Director, Operations & Technical



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Director & Former USFDA GMP Inspector



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Technical Head MENA Region



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