inSeption GROUP

Customizable Strategic Solutions

Restoring Business Trust and Confidence

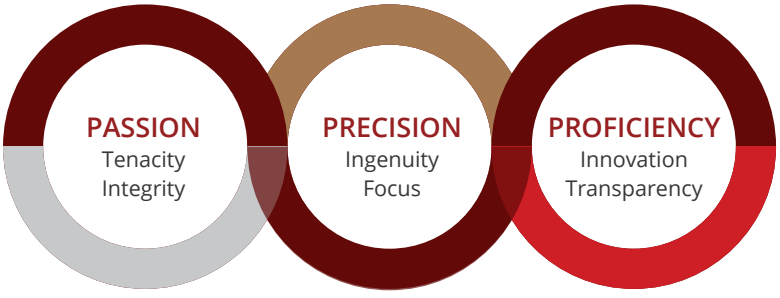
The inSeption Group Difference

inSeption was built on the foundational principle that quality outsourcing solutions must consist of the RIGHT people. Our collective passion to bring treatments and an improved quality of life to patients, unifies us in our mission to change the outsourcing paradigm.

Our path-breaking model attracts biopharma companies who demand a partner that shares in their drive to conduct impeccable development and will provide quality and dependable clinical solutions. We best serve operational leaders who also distinguish people as the most impactful variable in the outsourcing equation.

Our ability to attract the right people is our greatest asset.

Core Values



Expectations for excellence:

- Quality is the center of all activities
- Transparent communications
- Seamless integration with client team
- Personal accountability and responsibility
- Cost-effective solutions tasks are accurately completed the first time
- Collaborative risk mitigation
- Project teams built around specific knowledge and passion for a study subject
- Teams that see the study through

Global Regulatory Documentation Group

inSeption provides medical writing services as well as strategic submission planning expertise to ensure that your application is of the highest quality. Our highly experienced, fully dedicated team integrates with your organization to credibly manage the complexities of timeline creation and management, resourcing, document interdependencies, and transmission through the Electronic Submission Gateway (ESG).

Medical Writing

› Global regulatory submissions, Modules 2-5 of the eCTD

› CSRs (Phase 1-4)

› Orphan Drug Applications

› Investigator's Brochures

› Clinical Protocols and Amendments

› Safety Narratives

› Annual Reports

› Briefing Books

› Responses to agency questions

› Pediatric Study Plans and Pediatric Investigation Plans

› Publications (abstracts, posters, manuscripts)

› Public disclosure writing

Quality Control

› 100% QC of all documents

› Verification of consistency across all documents

Regulatory Operations and Submissions

› Document-level formatting and publishing

› Publishing and maintenance of eCTD submissions

› Transmission to health authorities (ESG)

› Strategic consulting and process optimization

Overview of Expertise

inSeption's Global Regulatory Documentation Group provides seamless collaboration on documents and submissions throughout a spectrum of services: medical writing, quality control review, document- and submission-level publishing, and health authority submission management.

We have the flexibility to manage all aspects of your regulatory writing program, either as a fully-dedicated partner or as individual contributors to fit within your existing team.