inSeption GROUP

Customizable Strategic Solutions

Restoring Business Trust and Confidence

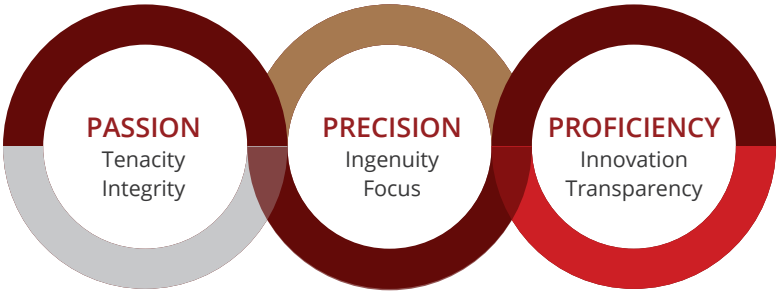
The inSeption Group Difference

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

Regulatory Operations

The Challenge

Obtaining approvals of investigational and marketing applications, guided by years of research and development, can be an enormous task. Regulatory and technical requirements for submission of applications are always evolving. Meeting these requirements can be costly, time consuming, and involve interpretation and global understanding.

The Risk

Business functions are often expected to understand and apply the technical submission requirements. Failure to comply with these rigorous technical requirements can lead to delayed approvals or worse, rejection of applications.

Our Solution

Our professionals have been navigating the complexities of regulatory and technical requirements for decades. We offer resources with vast experience and a passion for improving public health. We follow ICH and regional guidance documents from agencies globally to ensure the compliance of submissions and to enable seamless review by health authorities.

We partner with our sponsors to ensure timely, compliant, and high-quality submissions of investigational and marketing applications. We support the sponsors in assuring the safety, effectiveness, and quality of human drugs, biologics, and medical devices.

Let's have a conversation about how you can leverage inSeption's people, validated tools and technology from Day 1. Our solutions are flexible and seamless!

Formatting and Publishing

- Perform MSWord Document Formatting
- Perform PDF Publishing of single/multiple document components e.g., CSRs:
    - Bookmarking and hyperlinking
    - Image cleaning and orientation
    - Legacy and granular report publishing
    - OCR and File optimization

Submissions Management

- Provide submissions project management and guidance
- Publish and maintain eCTD submission:
    - Application/Sequence Set-up
    - Build eCTD
    - Apply study tagging requirements
    - Update leaf titles
    - Cross-application linking
    - Submission validation
    - Transmission to health authority e.g., ESG Gateway

Strategic Consulting

- Conduct gap analysis to assess current and future publishing efforts
- Provide eCTD Training
- Provide guidance on application, sequence, study structure and metadata
- Develop publishing and submission-specific SOPs
- Ensure process optimization
- Consult on tools and systems implementation initiatives
- Develop submission style guide