



Cell and Gene Therapy In-a-Box for Life Sciences

Empowering Early-Stage Cell and Gene Therapy (CGT) Companies to Scale and Grow

Navigating the complex landscape of cell and gene therapy can be challenging for early-stage companies. From insufficient document management to a lack of clear framework, all the way through needing expert regulatory submission insights, it can be difficult for Cell and Gene Therapy organizations to find the necessary support and tools to navigate the commercialization process alone.

These challenges can create inefficiencies that block scalability. That's why it's crucial to have a robust solution that provides total support while minimizing errors and streamlining processes.

INTRODUCING THE CELL AND GENE THERAPY IN-A-BOX SOLUTION

Developed in collaboration with IQVIA, Cell and Gene Therapy In-a-Box Solution is your comprehensive playbook designed to guide CAGT organizations through the commercialization pathway with essential tools and support.

Cell and Gene Therapy In-a-Box Solution Includes:

CUSTOMIZED ROADMAP

Navigate key events in bringing a product to market with a clear, step-by-step plan.

CROSS-FUNCTIONAL ORCHESTRATION

Leverage standardized best practices, support, and planning for submission and inspection readiness.

KNOWLEDGE MANAGEMENT PLATFORM

Enjoy validated document storage and a comprehensive audit trail for regulatory compliance and version control.

And So Much More.

Equip your company with a clear understanding of foundational success factors and potential roadblocks for successful product submission. Plus, benefit from a tailored plan specific to your organization's needs and access expert support throughout, so your team isn't moving through the process alone.

DISCOVER REGDOCS365'S CGT IN-A-BOX SOLUTION

RegDoc365's CGT In-a-Box is a fully 21 CFR Part 11 compliant, cost-effective content and document management solution hosted in an Audit Ready Compliant Cloud (ARCC) validated environment.

KEY FEATURES

Centralized Content Management

Manage all digital content, including documents, data, voice, and video, to streamline the commercialization process from discovery through post-market.

Inspection-Ready Documentation

Ensure your documentation is ready for quick and accessible audit or regulatory requests.

Complete Compliance Tools

Folder structures, checklists, workflows, alerts, and audit trails to help meet Good Management Practices and regulatory requirements.

REGDOCS365 & IQVIA OFFER AN INTEGRATED SOLUTION THAT INCLUDES

Project Management

Calendar Setup

Internal and External Collaboration Capabilities

Security and Data Governance

Document Library Repository

Dashboards for Quick Analysis

ABOUT COURT SQUARE GROUP

At Court Square Group, we specialize in Audit Ready Compliant Cloud Infrastructure solutions for the life sciences industry. Our cloud, collaboration, and regulatory submission solutions reduce costs, complexity, and risks associated with sharing, storing, and submitting information for regulatory requirements at every development and manufacturing lifecycle stage.

Ready to streamline your cell and gene therapy commercialization journey?
Contact us today to learn how CGT- In-a-Box can transform your business.



 courtsquaregroup.com

 info@courtsquaregroup.com

 413-746-0054

