QbDVision®

Accelerate Breakthroughs with Digital CMC™

Experience the benefits of structured data over document-based knowledge management to accelerate therapies to market.

KNOW WHERE. KNOW HOW. KNOW WHY.

The Challenge

The challenge has always been one of dispersed and unstructured data. Over the long trajectory of process development and validation, data is buried in documents, spreadsheets, flowcharts, and other files which are then stored in a myriad of file servers, quality management systems, and databases that are not integrated. As a result, CMC knowledge is dispersed and hard to find, data utilization and integrity are poor, preparation of regulatory submissions and tech transfer are cumbersome, and product lifecycle management is reactive.

The Solution

If the problem is the lack of structure and poor centralization, then the solution is **QbDVision®**. QbDVision is a Digital CMC™ platform redefining how software can capture the evolution of product and process development as a structured dataset. This data-centric approach moves process validation, tech transfer and CPV away from inefficient document-based frameworks to more efficient digital structures.

For the first time, the multiple dimensions of CMC such as requirements, risk, analytics, facility, quality, and control come together in a vertically integrated, digital knowledge base. This integration simplifies key workflows, automates compliance, addresses operational inefficiencies and advances digital maturity to accelerate therapies to market using best practices while ensuring product quality.

The Benefits

Digital CMC™ Knowledge Base

Structured repository centralizes product and process information within a compliant, framework that captures knowledge over time.

"Right-First-Time" Development

Organize multiple streams of data aligned with workflows based on ICH/QbD best practices to get it right the first time..

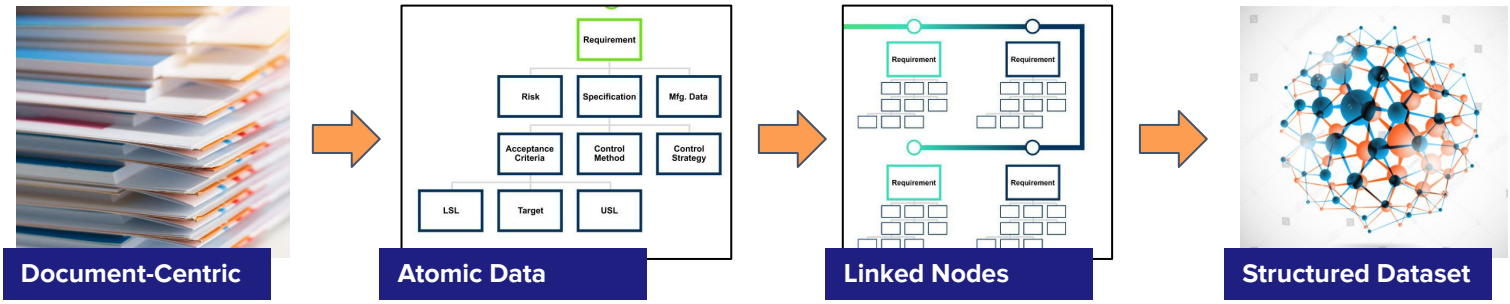
Digital Tech Transfer

Simplify and shorten tech transfer dramatically with real-time gap and risk assessments between digital views of the sending and receiving sites.

Digital Process Validation

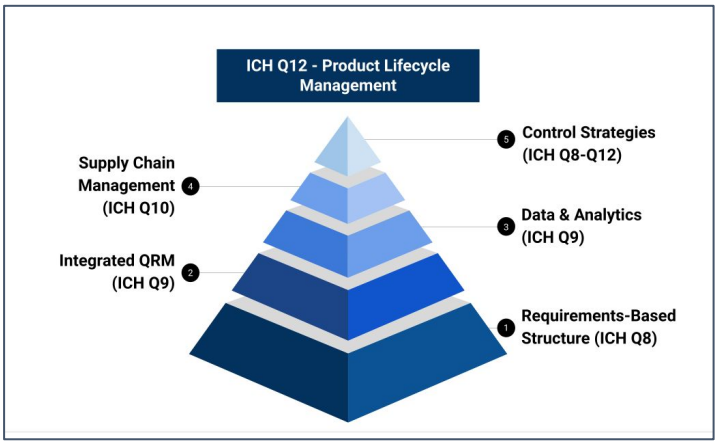
Track all aspects of the manufacturing process and quickly assess for operational readiness and performance relative to final specifications.

Structuring CMC Data is the Key



Document-Centric | **Atomic Data** | **Linked Nodes** | **Structured Dataset**

Deploying Digital CMC starts with converting unstructured data in document-centric systems into individual (atomic) nodes of data each broken down further into constituent elements. These nodes are then linked to form a highly structured data set that can be easily searched and visualized. The QbDVision platform has been developed to allow companies to quickly deploy a Digital CMC approach and realize its operational benefits.



Structure Needs Context

Making CMC data more atomic only addresses the challenges of document-centric systems partially. Ensuring that this data is structured with the appropriate context is also critical. For pharma and biotech products, the International Conference on Harmonization (ICH) has provided an architecture that is endorsed by regulatory agencies and the industry globally. QbDVision leverages this architecture to create a structure where requirements form the foundation of the Digital CMC knowledge base.

Digital CMC™ and the Evolution of Process Knowledge

Structured data is no longer optional. Traditional approaches to development for a new drug product can take as long as 7-8 years to complete. During this period, vast amounts of data are generated on the product formulation and manufacturing process, including recipes, materials, equipment, and more. Digital CMC brings consistency, standardization, and context. Shared access then enables collaboration with this contextualized information. As teams explore and characterize the evolving process from early development to production and CPV, a deeper understanding and intelligence emerges which can be used to demonstrate robust process control and accelerate technology transfer activities digitally from one organization, or one site, to another.