

INTRODUCTION TO CHEMISTRY, MANUFACTURING & CONTROLS (CMC)

Scientist.com understands the importance of ensuring that any provider of Chemistry, Manufacturing and Controls (CMC) services adhere to the highest standards with respect to sourcing and provision. We also recognize there is an opportunity to reduce the administrative burden associated with CMC service acquisition to enable greater focus on the science without compromising the quality and compliance checks.

It is for this reason we have expanded COMPLi® to support CMC. COMPLi is an award-winning compliance solution that enable Clients to streamline their due diligence processes, whilst providing suppliers to ability to efficiently promote their internal policies and procedures.

COMPLi Functionality:



Visibility:

- Transparent legal terms developed specifically for HBS acquisition
- Increased access to various sample types



Traceability:

- Visibility to Sample Information (consent status, virology status, etc.)
- Project tracking information centrally captured and auditable



Control:

- Align with internal policies to guide researchers
- Decide who you want to work with while communicating directly with the key stakeholders
- Apply relevant reviews and approvals (not just financial) prior to acquisition

2

Days to go from request to quote

~26%

Average percentage savings per order

300+

Signed CMC suppliers on the marketplace

Chemistry, Manufacturing and Controls (Challenges):

- Diverse Supply Base – Complex Regulatory Requirements - Logistical challenges

Scientist.com Solution Supports:

- 20,000+ researchers by giving them access to over 500 global CMC suppliers
- 100+ pharma and biotech clients by providing customizable framework for legal & compliance (COMPLi) alignment

Scientist.com Solution For:

- Proactive access to critical information
- Reducing the administrative burden related to CMC provision and acquisition
- Improving transparency, control and visibility of CMC related activities within your organization

COMPLi was designed to address the core challenges faced by industry when sourcing CMC services. It is made up of the following components:

Service Specific Due Diligence

- A CMC specific written pre-assessment tool and a Raw Material specific written pre-assessment tool to enable a supplier to communicate critical information to clients of Scientist.com in a single process, addressing the needs of multiple global biopharma
- Suppliers have full control over the information provided and can update at any time, while the clients retain an independent decision

Pre-negotiated Agreement

- Working with industry and providers, Scientist.com has developed a CMC specific amendment to our Research Services Agreement to specifically address the requirements of both Clients and Suppliers

Compliance Functionality

- COMPLi is comprised of a suite of features to support compliance interactions based on your internal policies and procedures enabling enhanced communication between suppliers and researchers

CMC Sourcing Via Scientist.com

- The marketplace has supported hundreds of CMC requests from a global industry base since 2018
- Increased visibility and access to various services covering Raw Materials, Analytical Development and Validation, API and Drug Product Stability Testing, and Drug Substance and Drug Product Characterization and Manufacturing
- Additional technical RFIs to enable a supplier to proactively communicate their experience and capabilities that can be accessed by researchers at the time of supplier selection
- Project tracking information centrally captured and auditable
- Empowered compliance decision making
 - Decide who you want to work with while communicating directly with the key stakeholders
 - Apply relevant reviews and approvals (not just financial) prior to acquisition

For more information email:

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