Data Sheet





Accelerating Product Development for Life Sciences



# Accelerating Product Development for Life Sciences

As life science companies advance their products through the R&D lifecycle, the focus gradually moves from hypothesisdriven research and screening to more controlled, methodical development. The development phases often require a more structured approach to data capture, and fall under the scope of regulatory compliance and validation. Often this drives companies to use disparate IT solutions, making it increasingly difficult for Research and Development teams to collaborate across phases. These challenges slow down how breakthrough science gets to market.

Benchling Validated Cloud makes it possible for Research and Development teams to operate from a unified, validated informatics solution. Research teams can leverage Benchling's widely adopted applications for molecular design, registration, and experimentation. Development teams can advance programs using the same solution, although within a secure, compliant, trusted environment that can withstand the rigors of regulatory validation.



#### With Benchling Validated Cloud, R&D organizations benefit from:

Improved tech transfer between Research and Development phases

Established and maintained validation requirements, compliance, and quality

Faster assembly of data packages for regulatory filings

## Dedicated tenant for validated applications

Greater control and compliance without an impact to work done in non-validated tenant environment

Controlled, quarterly product release cycles

### Application controls to ensure user compliance

Electronic signature control on all entries, with records becoming locked and noneditable upon signature per 21 CFR Part 11 (U.S.) and Annex 11 (E.U.) regulations

Complete audit trail with strict versioning of all edits and visible timestamps

Controlled user access to track and trace engagement and changes

### Validation process support

Quarterly validation packages that detail the changes and potential impacts

Validation Plan and Impact Assessment to help determine the risk level of changes to use of Benchling

Supporting documents to facilitate validation process (IQ, OQ, PQ, UAT)

<del>@</del>	СНО Х			
	METADATA		DESCRIPTION RESULTS STORAGE DASHBOARD	•
Ê			Cell Line 🧊	0
۹	CHO Registry		C C	
+	Authors	Project Location		
	Johan Sunryd	🛅 Chemical Screen 📩	Chemical Luciferase Screen with CHO Cells Z	
	Registry IDs CL007	Created 11/24/2020 10:57 AM	C01000733 - 2020-09-15 C01000733 - 2020-09-09 C01000133 - 2020-10-01	
	Chemical Screen Antibodies	1/24/2020 10.07 AM	CO1000133- 2020-11-24	
	Aliases +		30000	
	This entity has no aliases.		e 25000	
	This entity has no allases.		20000	
	Schema	Edit	15000	
	Cell Line	~	10000 9W 5000	
	Cannot change schema of registered entities		0-	
6	FIELD	VALUE	0 10 20 30 40 50 60 70 80 90 100	
	Name	СНО	Concentration, uM	
	Species	Chinese hamster	CHO Cell Line Inventory 2	
	Tissue	Ovary		
	Source	ATCC	Cryovial Cell Line Cells/mL Box Shelf Freezer	
	Lot Number	CHO-48957	1 J CV008 CHO 4000000 CV Box 1 B Sheif 1 B-80 C Freezer A	
	QC review	Yes	2	

"We are always looking to improve our efficiency and grow. Our research teams have been using Benchling for years, seen impressive results, and are particularly reliant on the solution's powerful collaboration capabilities. With Benchling Validated Cloud, we can now also meet regulatory compliance requirements and operate within the constraints of our rigid LIMS system. Having one R&D data management solution allows us to carry forward insights and workflows into the more structured and controlled development processes, giving us a real competitive advantage."



Nermin Avdispahic Quality Control Manager



# A unified application suite to connect R&D phases

Benchling Validated Cloud supports common lab operations with controlled, compliant applications for:



Experimental design and methods

Sample and reagent management





Team collaboration and review



Data analytics and analysis

enchling Validated Cloud	
Target ID / Validation	
Screening	
Lead Discovery	Lead Optimization
Cell Line Development	· · · · · · · · · · · · · · · · · · ·
	In Vivo Studies
	Process Development
	Analytical Development / Testing
	Bioanalytical Development / Testing
	Formulations
Research	Development

## Helping customers with the validation lifecycle

### **Benchling Professional Services**

provides full-service implementation support for Benchling solutions, and can also be leveraged with accredited third-party consulting firms. Every implementation consists of detailed project plans led by dedicated project teams staffed by experienced and knowledgeable Customer Experience professionals that can be consulted on software validation, Performance Qualifications, and User Acceptance Testing.

### **Benchling Managed Services**

offers ongoing services to Benchling customers to support quarterly release management, staff augmentation, and other functions related to Benchling implementations.

### Traceability, accountability, and data integrity

Benchling is committed to maintaining the highest standards for validation, compliance, and security. Benchling's controls, infrastructure, and processesensure the product meets and exceeds applicable statutory and regulatory requirements. Benchling Validated Cloud is ISO 27001 certified for security compliance and aligned with ISO 9001 QMS guidance.