

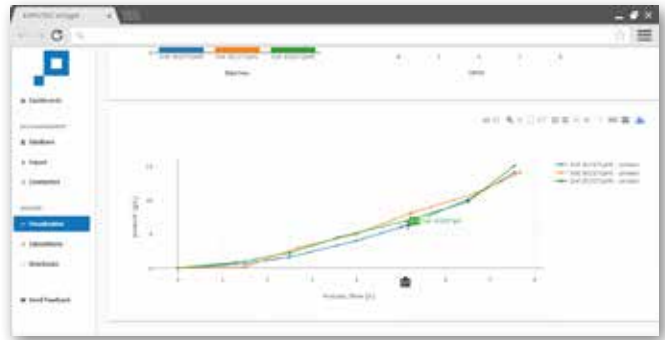


inCygnt[®]

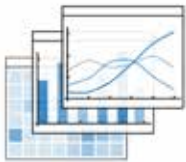
Process Data Management and Analytics Software

**Analyze all your data.
Fast. Clean. Intuitive. In real-time.**

Become a highly adaptive biotech company with Exputec inCyght®. The software can help you integrate all unit operations for the complete product life cycle. Connect your people, and departments such as quality, process development, validation and operations. This ensures safe and robust process design for small and large scale. Accelerate your commercialization including regulatory filings with inCyght. Get the process intelligence and visibility you need to run your biotech processes in real time.

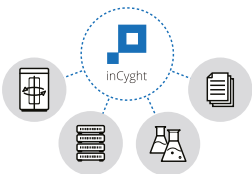


Key Features



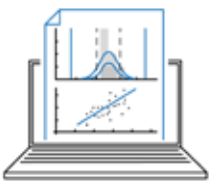
Intelligent Data Visualization for all Unit Operations

inCyght® offers an intuitive visual analytics environment for the intelligent visualization of all process data types. The unique inMatrix visualization concept intelligently selects the right visualization scheme for your process data. This enables scientists and engineers to simultaneously plot data from all unit operations to detect trends and correlations.



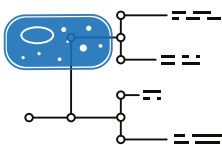
Flexible Data Management for Laboratory and Manufacturing

inCyght® offers management of time series, sensor, quality and spectral data as well as video- and image data. A broad spectrum of customizable database filters enables you to quickly identify relevant batches, unit operations and data types required for your analysis. The out of the box data management functionalities are ideal for process development, process validation and quality trending/ biosimilarity activities. inCyght® offers fast integration of all process relevant data sources via real-time connection to laboratory equipment and high throughput process development equipment, drag&drop browser import for tabular data as well as server crawl functions.



The Must-Have Toolbox for Statistical Analysis

Similarity analysis features enables user-friendly and statistically sound analysis of scale-ups, technology transfers and unit operations. Using multivariate and univariate statistical tools engineers quickly identify processing trends and correlations. In addition, statisticians can directly connect to the database using R and Python connectors for advanced and flexible statistical analysis. The out of the box statistical tools fulfill the requirements for process validation, technology transfer and quality trending/ biosimilarity statistical analysis.



Strain Information Management & Analysis

inCyght® manages and visualizes strain geneologies. This enables scientists and engineers to freely explore genetic modifications performed on production strains in combination with strain performance and growth data. In addition, lab managers create the necessary GMO documentation according to the local GMO legislation.



FDA 21 CFR Part 11 Compliance

Exputec inCyght® features Audit Trail, Access Protection, Copies of Records, Record Retention, Electronic Signatures and a Validation Roadmap to meet FDA 21 CFR Part 11 and EudraLex Annex 11 requirements. For detailed information on the compliance package please download our whitepaper from exputec.com/incyght

Content Packages

Exputec's pre-configured content packages provide a jump-start for deploying Exputec inCygnt® to solve process development and manufacturing challenges. They are based on the industry's best practices and the know-how of Exputec consultants and reflect the requirements of bioprocess development, operation, as well as validation scientists and engineers.

Bioprocess Design, Analysis & Control

Exputec inCygnt® Bioprocess Analysis content packages offer pre-configured mass balancing workflows, soft-sensors and reporting templates to analyze and report bioprocess data. By using Exputec inCygnt® Bioprocess Analysis content packages along with the associated comprehensive consulting services, inCygnt® users extract maximum information from bioprocess data.

Content packs for following unit operations are available:

- Microbial fermentation
- Cell culture fermentation
- Preparative chromatography

Biopharmaceutical Process Validation

Exputec inCygnt® Biopharmaceutical Process Validation content packages along with the associated comprehensive statistical consulting services, provide a software guided framework and statistical tools for solving bioprocess development and manufacturing challenges.

Content packages for the following tasks during the bioprocess lifecycle are available:

- Scale-down model qualification
- Design- and execution of process characterization studies
- Analysis and reporting of technology transfer

Quality Trending & Biosimilarity

Exputec inCygnt® Quality Trending & Biosimilarity content packages along with the associated comprehensive statistical consulting services, provide a software guided framework and software tools for advanced data management, trending and statistical analysis of quality data.

- Management of all quality relevant data types (a.o. Bioassay, HPLC, ELISA)
- Univariate and multivariate analysis of similarity for biosimilar products according to state of the art methods
- Quality trending dashboards using univariate- and multivariate control charts

Functionality Comparison

Functionality	inCygnt® Viewer	inCygnt® Professional	inCygnt® Enterprise
Data Upload	✓	✓	✓
Data Visualization	✓	✓	✓
E-Mail Helpdesk Support	✓	✓	✓
Statistical Data Analytics		✓	✓
Feature-based Data Analytics		✓	✓
inCygnt Plug-Ins: 1 Plug-In included		✓	✓
User Management Administration			✓
Numerical Computing Environment			✓
Dashboard Development Kit			✓
inCygnt Server License (1 customer server)			✓
Real-time Process Connectors			✓
inCygnt SaaS Data Backup for 10.000 Batches			✓

Request a personal demo

We'd love the opportunity to demo inCyght® to your team, answer your questions and explore whether inCyght® could be a good fit.

You can reach us at
+43 (0)1 997 28 49 or
contact@exputec.com



Design to improve

EXPUTEC is committed to deliver scalability, efficiency and quality to product lifecycles in the (bio-)pharmaceutical, industrial biotech and chemical process industry.

inCyght® System requirements

inCyght® Fermentation Expert – Installed on the desktop PCs of the users

Processor	Intel Core i5 or higher, 64-bit CPU required
Memory	4 GB (8 GB recommended)
Hard drive	2 GB free space for installation, 1 GB after install required
Operating system	Microsoft Windows 7 or later (64-bit required)
Browser	Mozilla Firefox, Google Chrome or Microsoft Edge / Internet Explorer (10+)

inCyght® Web – Installed on a server and access via Intranet

Server	Different environments supported (e.g. Linux or Windows based, 64 bit required), Docker based installation
Processor	Multicore 64-bit
Memory	8 GB (depending on number of users)
Hard drive	6 GB for installation of software (SSD recommended) + additional storage for data
Client	Operating system Microsoft Windows 7 or later, Linux (64-bit required)
Browser	Mozilla Firefox, Google Chrome, Microsoft Edge / Internet Explorer (10+)