inCyght®

Process Data Management and Analytics Software
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

Expucet’s pre-configured content packages provide a jump-start for deploying Exputec inCyght® 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

Expucet inCyght® Bioprocess Analysis content packages offer pre-configured mass balancing workflows, soft-sensors and reporting templates to analyze and report bioprocess data. By using Expucet inCyght® Bioprocess Analysis content packages along with the associated comprehensive consulting services, inCyght® 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

Expucet inCyght® 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

Expucet inCyght® 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

<table>
<thead>
<tr>
<th>Functionality</th>
<th>inCyght® Viewer</th>
<th>inCyght® Professional</th>
<th>inCyght® Enterprise</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Upload</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Data Visualization</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>E-Mail Helpdesk Support</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Statistical Data Analytics</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Feature-based Data Analytics</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>inCyght Plug-Ins: 1 Plug-In included</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>User Management Administration</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Numerical Computing Environment</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Dashboard Development Kit</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>inCyght Server License (1 customer server)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Real-time Process Connectors</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>inCyght SaaS Data Backup for 10,000 Batches</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tbody>
</table>
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**: Multi-core 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+)