innerspace

Product Guide

Frame-by-Frame®

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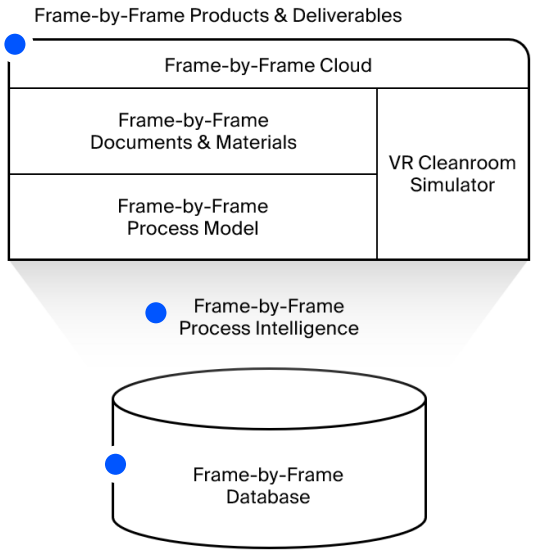
1 Executive Summary

Innerspace has developed Frame-by-Frame, a proprietary technology, which provides a new perspective on how aseptic processes can be systematically modeled, analyzed, and implemented. It is data-driven by design and provides a reliable and scalable foundation for aseptic manufacturing process management.

Traditionally, most process management of pharmaceutical manufacturing starts and ends with creating the necessary regulated documents and materials for existing processes. Innerspace changes that. With Frame-by-Frame, Process Models are created first, and then the corresponding set of documents and materials is derived. Frame-by-Frame can be introduced at any point in the aseptic manufacturing process lifecycle.

The Frame-by-Frame architecture consists of three layers:

- Frame-by-Frame Products & Deliverables (contain all elements delivered to and used by customers)
- Frame-by-Frame Process Intelligence (expert systems operated by Innerspace)
- Frame-by-Frame Database (expert systems operated by Innerspace)



1.1 Frame-by-Frame Database

The foundation of the Frame-by-Frame Architecture. It contains a large amount of process-related data organized in libraries for objects, actions, and associated hazard scenarios. These elements with their relations are the building blocks of Frame-by-Frame Process Models across all varieties of aseptic processes.

1.2 Frame-by-Frame Process Intelligence

The methodology and technology that Innerspace experts use to generate and analyze Frame-by-Frame Process Models. The Frame-by-Frame Process Modeling Language generates a digital process model from video recordings, SOPs, and other process description data.

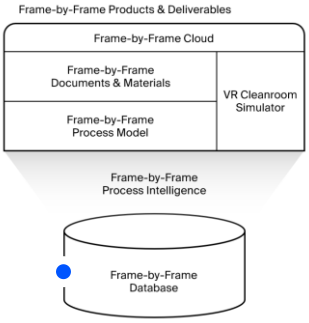
With Frame-by-Frame Process Analytics, the Frame-by-Frame Process Model is used for risk assessment and control. It allows risk assessment on all granularity levels, creates risk- and execution-focused documents and corresponding training material, all reliable and data-driven through its derivation from the Frame-by-Frame Process Model.

1.3 Frame-by-Frame Products & Deliverables

The Frame-by-Frame Cloud hosts all Frame-by-Frame Process Models, Documents & Materials as well as the cloud components of the VR Cleanroom Simulators of each customer.

Frame-by-Frame Process Models and the corresponding Frame-by-Frame Documents and Materials are the results of modeling and describing aseptic processes. The Virtual Reality (VR) Cleanroom Simulator provides principle-based training in VR for aseptic handling.

2 Frame-by-Frame Architecture - Details



2.1 Frame-by-Frame Database

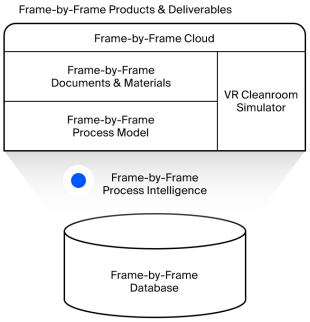
The Frame-by-Frame Database contains structured libraries for objects, actions, and associated hazard scenarios used within aseptic processes. These libraries provide the standardized data foundation for the creation and analysis of Frame-by-Frame Process Models.

The **object library** contains standard tools, materials, and process-relevant objects together with their associated risk-relevant properties, such as size, weight, handling characteristics, and interaction complexity.

The **action library** classifies and standardizes the actions and process steps performed within aseptic operations.

The **hazard library** contains hazard scenarios associated with objects, actions, and process conditions across different operational contexts within aseptic processes.

Together, these libraries form the basis for the creation of semantic, data-driven Frame-by-Frame Process Models representing complete aseptic manufacturing processes. The Frame-by-Frame Database is continuously expanded, reviewed, and maintained to support ongoing process modeling and risk analysis activities.



2.2 Frame-by-Frame Process Intelligence

2.2.1 Frame-by-Frame Process Modeling Language

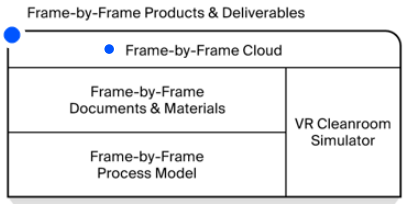
The Frame-by-Frame Process Modeling Language provides the methodology and technology required to build, structure, and analyze detailed Frame-by-Frame Process Models. By combining multi-camera video recordings, SOPs, and additional process description data with the Frame-by-Frame Database, the system transforms operational procedures into standardized, data-driven process representations.

These process models can consist of many thousands of interconnected frames describing actions, interactions, dependencies, and contextual process information. This level of granularity supports process analysis, risk evaluation, execution assessment, and the generation of structured operational and training outputs.

2.2.2 Frame-by-Frame Process Analytics

Frame-by-Frame Process Analytics enables risk assessment across different levels of process granularity. It generates risk- and execution-focused documentation, training content, and operational insights from the Frame-by-Frame Process Model. Hence, they remain consistent, traceable, and data-driven.

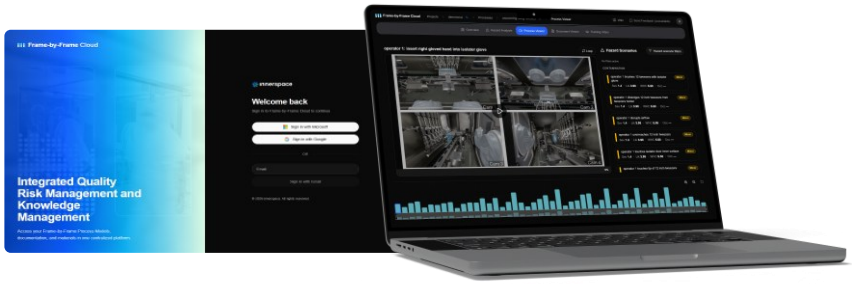
By standardizing the analysis of process parameters, actions, and dependencies, Frame-by-Frame Process Analytics can translate, quantify, and aggregate process risk through a structured methodology. This supports alignment and integration with established risk management methodologies and frameworks, enabling consistent and transparent risk evaluation across operations.



2.3 Frame-by-Frame Products & Deliverables

2.3.1 Frame-by-Frame Cloud

The Frame-by-Frame Cloud is the infrastructure for data and applications delivered by Innerspace. The infrastructure is hosted on Amazon Web Services (AWS) and is solely operated and managed by Innerspace. Each customer operates within a strictly separated multitenant environment.



Applications

Frame-by-Frame Process Explorer

Provides access to the Frame-by-Frame Process Model for applications including risk assessment, process sequence visualization, and risk control measures. The Process Explorer connects video recordings and/or simulations directly to the corresponding frame sequences. It visualizes detailed execution and the associated hazard specifications and risk data, enabling contextual process analysis and review.

Component	Benefit	Included in Full License	Included in Basic License
Viewer	Provides an interlinked view of the video/simulation, the Frame-by-Frame Process Model, and the corresponding Frame-by-Frame Documents and Materials.	✓	✓
Risk Assessment & Control	Provides granular, risk-based analysis of the process model to identify, assess, and manage risks and related controls.	✓	✗
Process Execution	Provides detailed operational guidance and process information to support consistent and reliable execution.	✓	✗
Training	Supports the onboarding, qualification, and continuous training of operational teams.	✓	✗
Change Control	Provides a controlled environment for creating model variations and evaluating their operational, risk, and documentation implications.	✓	✗

VR Cleanroom Simulator Platform

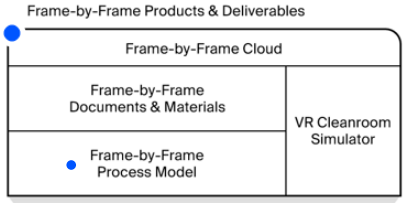
Provides analytics, reporting, and data management capabilities for the VR Cleanroom Simulator and its associated training programs. The platform also supports integration with customer Learning Management Systems (LMS), where available, enabling streamlined management of training records, user data, and performance results.

Data

The Frame-by-Frame Cloud hosts the Frame-by-Frame Process Models together with the corresponding Frame-by-Frame Documents and Materials generated from the models.

Furthermore, it also hosts the cloud-based components of the VR Cleanroom Simulator. VR Simulator stations deployed on-site download training modules and related content from the cloud environment, while training session data, analytics, and performance results are transmitted back to the cloud for storage, processing, and reporting.

2.3.1.1 Frame-by-Frame Process Model



Frame-by-Frame Process Models consist of individual Frames as their elementary building blocks. Depending on the complexity of a process, a model may contain many thousands of frames.

Frame: A frame represents the smallest meaningful observable action within a process (micro-process). Each frame consists of one subject (i.e., operator or robotic device), one action, and one or more objects.

Examples of frames include:

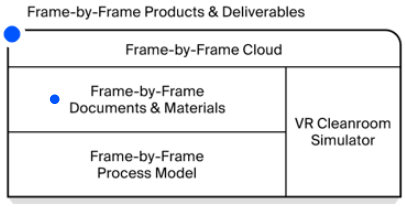
- *Operator 1: disinfect gloved hands with ipa spray*
- *Robotic arm: raise container*

Processes in or around critical manufacturing lines are subdivided into defined sequences of frames. Multiple frames are grouped into higher-level process components referred to as tasks. Tasks are further organized into sub-processes, which together constitute complete processes.

All Frame-by-Frame Process Models are hosted in the Frame-by-Frame Cloud, where applications provide different views and levels of detail depending on the use case.

The models use a proprietary format and can only be viewed in the Frame-by-Frame Cloud. It can neither be downloaded, viewed, nor edited using third-party applications.

2.3.1.2 Frame-by-Frame Documents & Materials

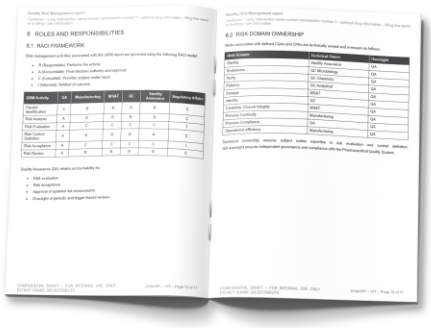


With Frame-by-Frame Process Models and the Frame-by-Frame Process Analytics, a set of corresponding documents and materials is created. They are the results of a breakdown and assessment of the processes, as well as a basis for guidance and training of operators.

All Frame-by-Frame Documents & Material elements are standardized and generated via a strict quality-controlled process. The majority of documents & materials are in standard office format and can be downloaded and further used in and with other systems.

Risk Assessment and Control

Risk assessment reports provide a structured overview of control effectiveness and the adequacy of risk mitigation within the process for compliance reporting purposes.



Available documents for Risk Assessment and Control are:

- *Quality Risk Management Report*

  Summarizes and references detailed risk assessments derived from the Frame-by-Frame Process Model.

Risk-based Improvements

A service that provides an analysis of potential improvements. They identify opportunities to reduce risk through potential adjustments to process execution or technical parameters, such as process steps, equipment interaction, operator positioning, sequencing, or other factors influencing hazard occurrence. If customers decide to implement changes, a subsequent review of the process model and the corresponding risk assessment documents will be necessary.

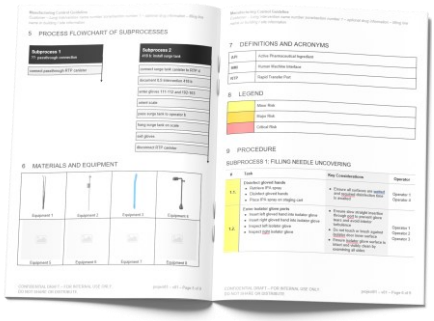
Available documents for Risk-based Improvements are:

- *Risk-based Improvement Analysis*

  Implementation of a process change will result in a Process Model and Risk Assessment Review with a reviewed Quality Risk Management Report.

Process Execution

This document family contains the necessary documents to operate processes properly.



Available documents for Process Execution are:

- *Work Instructions*

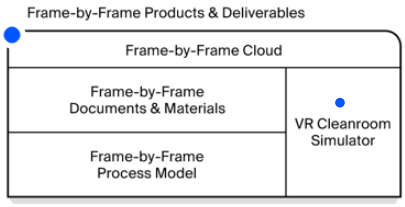
Training Material

The Training Material contains process-specific training content for personnel performing manual tasks. It includes training videos and corresponding knowledge assessments covering the most critical process steps.

Available documents for Training Material are:

- *Training Videos*

2.3.2 VR Cleanroom Simulator



The VR Cleanroom Simulator is a turnkey product that provides principle-based training using VR technology. It comes with a core package of training content for cleanroom behavior. Three add-on packages are available, depending on the customer's specific environment.

2.3.2.1 Training Content

- Introduction to Virtual Reality (included in Core Package)
- Aseptic Behavior Principles (included in Core Package)
- Cleaning & Disinfection Principles (Add-On Package)
- Environmental Monitoring Principles (Add-On Package)
- Aseptic Intervention Principles (Add-On Package)

Documentation and materials are included to support integration into GxP-validated environments. The VR Cleanroom Simulator product consists of an on-site hardware and software bundle, complemented by the VR Cleanroom Simulator Platform, a training management component hosted in the Frame-by-Frame Cloud.

2.3.2.2 Training Service

For customers of the VR Cleanroom Simulator, we offer a service package to increase the effectiveness of the principle-based training. This includes:

- Train-the-VR-trainer workshop

3 Appendix

3.1 Frame-by-Frame Process Model License Overview

	No Active License	Basic License	Full License
Frame-by-Frame Cloud			
Hosting of one Process Model and corresponding Documents & Materials	✗	✓	✓
Right to use Frame-by-Frame Database and Process Intelligence	✗	✓	✓
Frame-by-Frame Process Explorer			
Viewer	✗	✓	✓
Risk Assessment & Control	✗	✗	✓
Process Execution	✗	✗	✓
Training	✗	✗	✓
Change Control	✗	✗	✓
Service and Support			
Change of existing Process Model and corresponding Documents & Materials	n/a	individually quoted	10% of interventions or equivalent are included per year in license SLA: 5 business days until start of work
Technical Support	✗	✓	✓
Software updates	✗	✓	✓

Contact

Innerspace GmbH
Helga-Krismer-Platz 1
6020 Innsbruck, Austria

Innerspace US Inc.
1213 W Morehead St #505
Charlotte, NC 28208

T: +43 660 140 0971
E: office@innerspace.eu

www.innerspace.eu

innerspace