Figurate™ DCS automation solutions

POWERED BY EMERSON'S DELTAV™ CONTROL PLATFORM

Product overview

Figurate™ automation, powered by the DeltaV Distributed Control System (DCS) is a bioprocess automation software solution that applies the process and equipment expertise of Cytiva to Emerson's DeltaV DCS platform. It contains a library of control software to rapidly and reliably integrate Cytiva process equipment and can be applied in both GMP and non-GMP facilities.

The Figurate library is pre-tested and pre-verified in compliance with regulatory requirements, Good Automated Manufacturing Practice 5 (GAMP5), and ISO 9001, and is delivered with a comprehensive verification documentation package.

Fig 1. Figurate automation for DeltaV DCS.

The benefits

By adopting Figurate automation for DeltaV DCS, you can easily align your software horizontally across sites and vertically within your process development and manufacturing organizations.

The Figurate library is designed to:

- add process systems both local and international using a pre configured and pre-verified software library so you can easily expand equipment and automation.
- ensure automation is consistent, efficient, and reliable allowing you to deliver with minimum time and effort between project kickoff and closeout.

Table 1. Design specifications.

Design specifications

Item	Design description	Options available
Configuration basis	PCSD v13. Software library is built using PCSD v13 as its basis	N/A
DeltaV version	v13.3.1	v14 or greater
Graphics	iFIX PCSD HCD v13	DeltaV Live
Compatible with customer DeltaV systems	Yes. Figurate library elements are designed with a unique prefix applied to allow for integration with your systems without impact to existing configuration	N/A
DeltaV hardware	N/A	Available as project customization
Tagging	Cytiva standard tags (e.g., R01 for Xcellerex™ XDR biorector)	User specified tag names as customization
DeltaV batch	Phases and basic operations included	Recipe configuration per customer specification as customization
Enterprise application	Figurate automation for DeltaV DCS can be applied to FlexFactory™ configurable biomanufacturing trains and KUBio™ facilities	N/A
Language	English	N/A

Design and verification

Figurate automation for DeltaV DCS is a comprehensive platform designed to control Cytiva's manufacturing process equipment, and it leverages 20+ years of process and DeltaV expertise.

The platform configuration is based upon Emerson's PCSD v13 library and Human Centered Design (HCD) graphics and is well suited for use in applications from process development to GMP manufacturing. The Figurate software is designed to provide all elements needed to operate Cytiva process equipment manually or via batch within the DeltaV control system. Whether being applied to a new or existing system, the Figurate software is designed such that it will not conflict with other software.

Figurate automation for DeltaV DCS has been developed and verified in accordance with Cytiva's quality management system (QMS), which is certified to ISO 9001. Figurate software products are designed for Good Practice (GxP) regulated environments and for maintaining electronic records. These products are developed in line with GAMP 5 and related good practice guides (Fig 2). The software uses functionality supplied by the Emerson DeltaV platform that enables end user compliance with FDA 21 CFR Part 11 and EU GMP Annex 11.

For more information regarding the design and verification, please refer to the validation support file located on the Cytiva regulatory website. For instructions on how to access the regulatory support documentation, please review the videos in the following link.

Scope of delivery

Software

The Figurate library includes all Delta V software elements necessary to operate Cytiva process equipment, whether delivering a full facility or a single unit operation (Table 2).

Documentation

Standard documentation provided as part of a project delivery of a Figurate automation for DeltaV DCS unit operation (see Table 3).

Table 2. Software delivered.

Software element	Description
Named sets	Both common element and unit specific named sets are provided.
Setup data	Cytiva common engineering units, alarm priorities, and alarm types are provided.
Composites	Composites (both common and unit specific) are provided.
Control module classes	Control module classes (both common and unit specific) are provided.
Equipment module classes	Equipment module classes (both common and unit specific) are provided.
Unit module class	Unit module classes are provided.
Phase classes	Phase classes are provided.
Recipes	Basic operations are provided to demonstrate the setup of Figurate phases. Complex operations and unit procedures are developed as a project customization per customer specification.
Input/output (I/O)	I/O definition files and I/O configuration are provided.
Graphics	Graphics (batch, overview, unit specific, faceplates, and detailed faceplates) and graphical elements (dynamos, user settings file, global files, etc.) are provided (1920 × 1080). **Note:** iFIX graphics are included with the unit software. DeltaV Live graphics are available for purchase.
Charts	Library charts (common and unit specific) are provided. Custom charts can be provided upon request.
Unit instance	This includes instantiation of all unit modules, equipment modules, control modules, graphics, charts, I/O, and parameter values for all of the above.

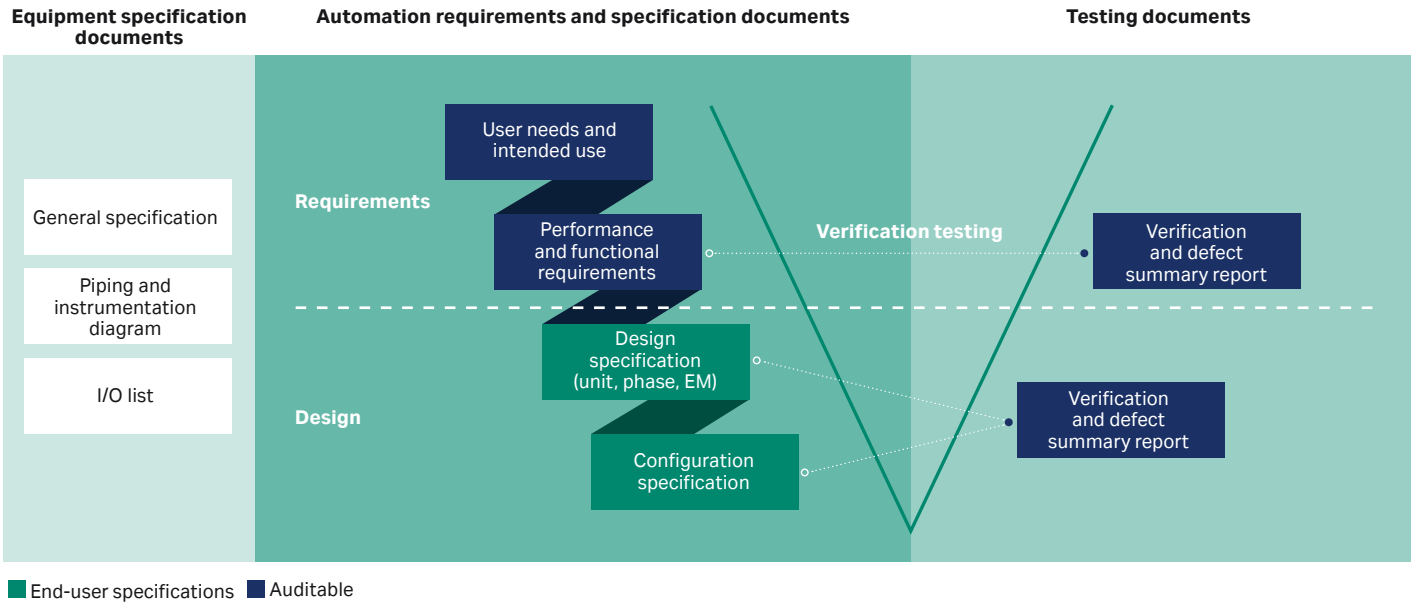

Fig 2. The product development V-model.

Table 3. Standard documentation delivered as part of a project delivery of a Figurate automation for DeltaV DCS unit operation.

Product document	Description
Unit functional specification (FS)	This functional specification identifies the functional requirements of the unit operation.
Design specifications (DS)	These documents describe the software elements such that they can be configured to achieve the functionality described in the unit functional specification. Documents included: unit DS, phase class DS, equipment module DS, control module DS, common elements DS. To be provided in PDF format. Native format (.docx) available as project customization.
Configuration specification (CS)	This document defines the configured parameter values for a given coding element. Documents include: graphics configuration specification (CS), setup data CS, equipment module instance CS, and control module CS. Format of delivered file/document may vary by file.
I/O list	The I/O list defines the I/O points for a unit operation as well as the configurated parameters for those I/O points.
Unit user manual (UM)	The user manual provides users with general information on Figurate automation powered by DeltaV DCS software for a given unit operation. The user manual provides instructions describing how to manage the product via the distributed control system in a safe way.
Software white paper	This document provides information regarding how to access the validation support file (VSF) from Cytiva's regulatory website. The VSF describes the development and documentation of Figurate automation for DeltaV DCS software. Available via download from the Cytiva website.
Database merge procedure	This document describes in detail the steps that are followed when importing Cytiva software into an end-user DeltaV system (if in scope of the project).
Database merge procedure test report	This report summarizes the outcome of the testing that is done after Cytiva software is imported into an end-user DeltaV system (if in scope of the project).

Note 1: The above table lists only the typical documentation deliverables for Figurate software. Additional documentation will be delivered with your Cytiva system that covers hardware features. Additional software documentation may also be delivered depending on the scope of the project.
Note 2: Product and project testing documentation are considered internal Cytiva documents and are available for review via audit.

End-user license agreement

Cytiva delivers its proprietary DeltaV software configuration and related documentation under license agreement. The software and documentation can only be used on the serial number of the bioprocess hardware system that the software was sold with.

The configuration can freely be changed or modified by the end-user but cannot be copied or re-used in whole or parts for use on other equipment.

Exclusions

Not included with standard Cytiva delivery:

- DeltaV hardware and licensing
- server, computer, and network hardware

Supported hardware systems

Figurate automation for DeltaV DCS is available for the upstream and downstream bioprocess hardware systems summarized in Table 4. See Table 4 for functional applications and specifications for each unit operation. If you don't see the system that you desire within the table, please reach out to your Cytiva representative to ask about additional available units and/or the possibility of delivering your unit as a custom request.

Biomanufacturing capacity solutions

Cytiva biomanufacturing capacity solutions, which include KUBio modular facilities and FlexFactory configurable biomanufacturing trains, enable both speed and flexibility. This solution is configurable with respect to equipment, automation, and service levels. The FlexFactory configurable biomanufacturing train is delivered as a turn-key solution, designed and executed by the Cytiva enterprise organization to ensure integration efficiency.

Explore Cytiva's modular single-use offering here.

FlexFactory projects utilizing Figurate automation for DeltaV DCS provide a configurable automation solution that delivers the features of automated stand-alone equipment, or unit ops working in coordination and connected to a centralized automation infrastructure.

Table 4. Cytiva systems.

Unit name	Application(s)	Description
ÄKTA ready™	Chromatography	ÄKTA ready is a single-use liquid chromatography system built for process scale-up and manufacturing. The system uses disposable flow paths and prepacked columns that enable flexibility and speed in bioprocessing.
ÄKTA ready XL	Chromatography	ÄKTA ready XL is a single-use liquid chromatography system designed for manufacturing.
ÄKTA readyflux™ XL	Tangential flow filtration	ÄKTA readyflux XL is an automated single-use filtration system designed for production of preclinical material and manufacturing of GMP-compliant material.
Normal flow filtration (NFF)	Filtration	BioProcess™ NFF pump system is intended for transportation of fluids from a production bioreactor to NFF systems, for applications such as harvest clarification and viral filtration.
ReadyToProcess WAVE™ 25 rocker	Cell culture	The ReadyToProcess WAVE 25 rocker features integrated temperature sensors and load cells, designed for convenient handling and control of cell cultures up to 25 L.
Xuri™ cell expansion system W25 rocker	Cell therapy	The Xuri W25 rocker features integrated temperature sensors and load cells, designed for convenient handling and control of cell cultures up to 25 L within cell therapy applications.
Xcellerex APS	Perfusion, process intensification	Xcellerex automated perfusion system (APS) is a single-use tangential flow filtration (TFF)-based system that is designed to provide flexibility, reliability, and simplicity in upstream perfusion applications for both process development and production.
Xcellerex XDUO Quad intelligent single-use mixing system	Mixing, harvest	The Xcellerex XDUO quad intelligent plug-and-play single-use mixing system features powerful onboard automation capabilities, including in-line sensing and process control, combined with robust mixing and ease of use.
Xcellerex XDR 50 to 2000 single-use stirred-tank bioreactors	Cell culture	Xcellerex XDR single-use bioreactor systems provide scalable and robust stirred-tank performance for up to 2000 L in both cGMP and non-cGMP environments.
Allegro™ MVP single-use system	Filtration, chromatography, viral inactivation, media preparation	Allegro MVP single-use system is a fully automated bioprocessing system, providing flexibility and improved productivity in upstream and downstream single-use processing.
LevMixer™ and magnetic mixer systems	Mixing, harvest	LevMixer and magnetic mixer systems are available from 6 to 1500 L and features online sensors and robust mixing capabilities.

Services

Implementation services

Cytiva offers implementation services that deliver software solutions to meet your project needs. We have a highly skilled and experienced engineering and implementation team with a proven track record in delivering DeltaV solutions to customers.

You can improve the efficiency of your project significantly by leveraging the range of implementation services available. Implementation services are highlighted in Table 5 below.

Table 5. Implementation services.

Implementation service	Description
Software instantiation	The product software library is instantiated into the units that will operate in your facility. This includes software and documentation instantiation as well as the configuration testing necessary to ensure quality. This service is mandatory for all initial project deliveries. For specific requirements, request this information during your quotation process.
Customization	If your project needs a greater scope of automation solutions than is available in the standard Figurate offering, we can work with you to deliver the exact solution you need. Common customizations include delivery of DeltaV hardware and network infrastructure, software customizations, and process hardware customizations.
Site implementation	Our team can import the software onto your site DeltaV system and verify completeness.

Qualification services

A critical regulatory step in any automation implementation is the qualification of the software. Cytiva offers qualification services that you can purchase optionally to support your site validation master plan, as well as regulatory testing and submissions. Our predefined qualification packages provide you with quality and speed of delivery to help improve your project efficiency.

The full scope and details of the qualification service offering are available upon request.

Maintenance and support services

We offer support through our OptiRun™ service platform. OptiRun service offerings revolve around your needs to ensure our equipment and software runs optimally, your employees are productive, and the processes they use are optimized to provide continuous performance, reliability, and uptime. Whether you have in-house support teams or plan to rely (fully or partially) on Cytiva, we have flexible service offerings to meet your specific needs. For more information, visit the OptiRun web page.

Training services

Training services are quoted on request. The scope of available training will be developed in coordination with your FlexFactory project. For a full list of Cytiva automation training courses, visit Fast Trak™ education.

We can help you choose the right configuration

Determining the best fit for your current needs with a practical design for expansion in the future can be challenging. Planning for growth that enables you to use your existing automation infrastructure is good business sense. We have experience working with facilities, equipment, and software of all sizes, and can make sound recommendations that could avoid unforeseen issues.

Ordering information

For ordering information, please speak to one of our sales representatives.

cytiva.com

For local office contact information, visit cytiva.com/contact

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