



# iText 7 Core – Generating PDF reports for pharmaceutical industry monitoring and auditing

Process Control software for various industries. Read on to learn how they use iText 7 to generate regulatory compliant PDF reports in their PharmaMV Real-Time Manager.

## BACKGROUND

In the Pharmaceutical industry, manufacturers are increasingly embracing new technologies to provide greater insight into their processes, in addition to speeding up the time to bring new medicines to market. In recent years Pharmaceutical high-value manufacturing has seen a significant shift towards the online application of Process Analytical Techniques (PAT). The application of online spectroscopy, Chemometrics and calibration modelling allow Critical Quality Attributes to be predicted and monitored in real-time.

To address these needs, Perceptive Engineering worked in close collaboration with some of the world's leading pharmaceutical companies to develop PharmaMV: a comprehensive suite of software tools encompassing multi-variate analysis, modelling, data visualization, process monitoring, control, and optimization. The platform is used to detect and eliminate faults,

improve product quality, and optimize batch and continuous pharmaceutical process units.

PharmaMV was designed to meet the regulatory requirements of the Pharmaceutical industry, such as the United States Food and Drug Administration's (FDA) 21 CFR Part 11 guidance, which defines the requirements for computer-based systems in the Pharmaceutical and food manufacturing industries.

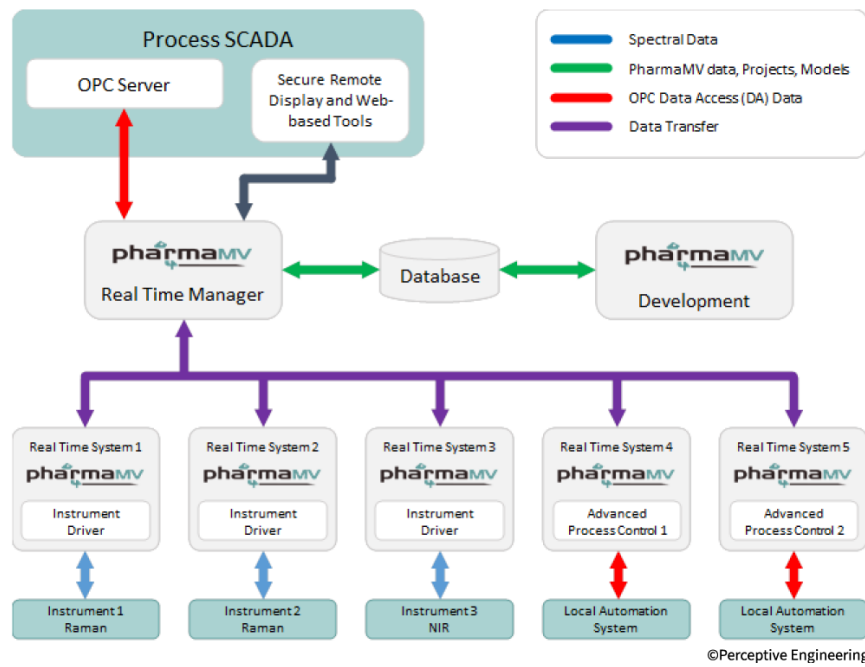
An important component of the platform is the PharmaMV Real-Time Manager (commonly referred to as RT Manager). RT Manager has the task of managing real-time stations where it is implementing the control and monitoring of processes. It provides version control and configuration reporting of projects and models through its inbuilt database. It allows seamless integration with production recipe/batch management systems. These features provide the ability to deploy PharmaMV applications in a distributed network.

## HOW RT MANAGER WORKS

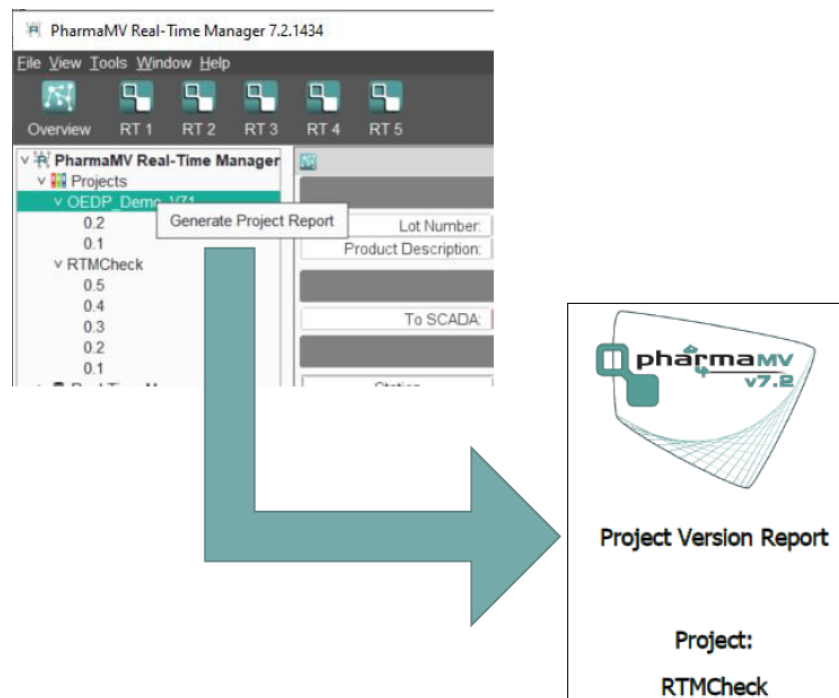
In the following diagram you can see how the RT Manager integrates into the PharmaMV solution. Data from the real-time systems across the bottom is managed and pulled together with the RT Manager, and data can be passed into a SCADA (Supervisory control and data acquisition) process, be sent to other systems, or go into a database.

RT Manager provides a general oversight of projects and applies a version control system to manage these projects. In each project version is contained complete information about the project, so that for instance any changes made will be accurately recorded.

RT Manager and PharmaMV work in combination to provide a distributed capability for all multi-variable techniques from PAT management and monitoring through to Advanced Process Control and Optimization. It allows manufacturers' investment in PAT to be maximized by providing all the tools required for process improvement in an integrated environment without the need for third-party software.



An overview of the PharmaMV solution, showing how the RT Manager provides oversight over real-time processes



A demonstration project in RT Manager showing how project version reports can be generated

## GOALS

- ✓ To produce various reports, containing data for project versions, summaries, configuration, events, and methods, to comply with industry regulations
- ✓ To present the required information in a manageable and consistent human-readable format
- ✓ To embed a PDF reporting engine and integrate it with their existing Java tools
- ✓ To easily handle large amounts of data and generate potentially huge reports

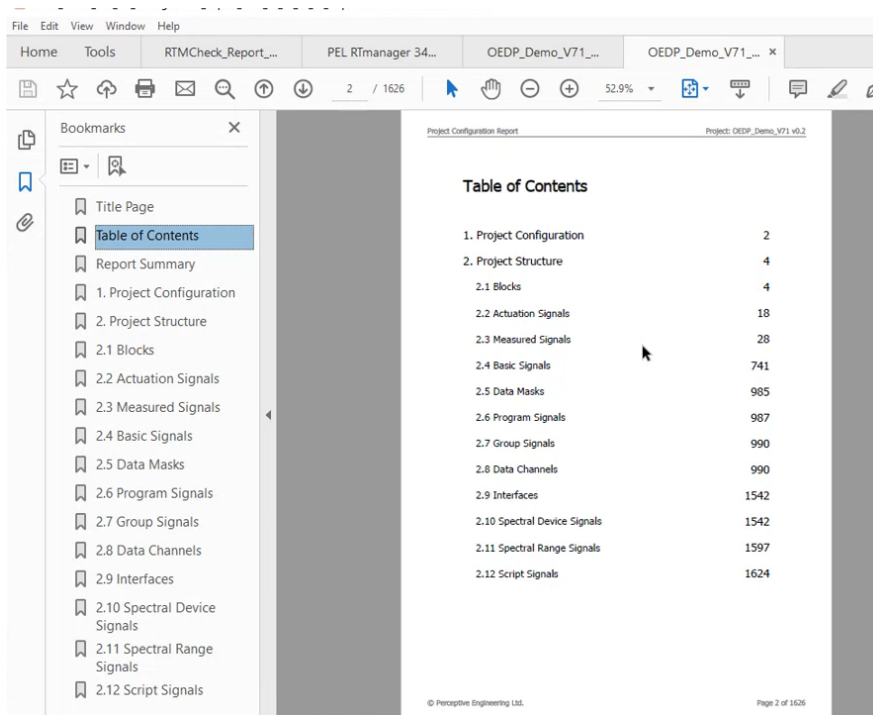
## CHALLENGES

The challenges Perceptive Engineering faced when developing their PharmaMV platform was to manage PAT instruments and associated data quality, methods and models in a regulatory environment, for the RT Manager however, the challenge was to display this information in a secure, yet human-readable form for accurate project tracking and auditing to take place. The industry regulations require manufacturers to present detailed reports of configurations, how systems are used, reports of any changes made, etc. for auditing by regulatory bodies.

The PDF format was a natural fit for this task, and so, a few years ago Perceptive Engineering looked into technologies which would allow them to produce PDF reports direct

from their products. The requirements were that it had to be available to run in Java, since their tools are Java-based. It also had to be easily embeddable, without needing to connect to any separate servers.

A crucial requirement though was the ability to handle enormous amounts of data, being able to generate massive, structured PDF configuration reports. These reports have the potential to run into thousands and thousands of pages, since they must contain all the details of a configuration for project tracking and auditing purposes.



An example configuration report generated from RT Manager, showing the dynamically-generated Table of Contents for easy report navigation

## SOLUTION

After investigating a number of options, Perceptive Engineering decided to integrate iText 7 Core into their RT Manager as it not only met but exceeded their requirements. By utilizing iText's commercial OEM licensing options, Perceptive Engineering could easily embed iText into RT Manager to produce the PDF reports they needed.

iText has been widely-used across many industries to embed PDF functionality into applications and processes, and is a versatile, programmable and enterprise-grade PDF solution. Being available for Java as well as the .NET platform, it provides a set of intuitive and consistent APIs together with a wealth of features for generating and manipulating PDFs which are compliant with ISO standards.

Perceptive Engineering's development team uses these APIs directly to enable RT Manager to dynamically generate reports with customized layouts, allowing data they contain to be laid out in a consistent, readable format, complete with PDF outlines for title pages, a table of contents, chapters, custom headers and footers etc.

A key feature of the RT Manager is the ability to quickly generate comparison reports. Since configuration details are stored as XML, they use the difference engine capabilities of DeltaXML to generate comparisons between configurations, which are then displayed as PDF. All of this can be achieved with just a couple of clicks, and the reports are generated on the fly.

## RESULT

iText was quickly integrated into RT Manager, and since the application launched in 2018 it has been utilized by Perceptive Engineering's customers within the industry, including one of the world's largest pharmaceutical companies. Generating huge configuration reports which commonly number many thousands of pages is no problem for iText with its enterprise-grade capabilities and standards compliance.

As for the future, Perceptive Engineering are looking into ways they can offer additional capabilities to their clients by utilizing more of the features iText 7 offers. In addition, they are closely following developments in other industries where their tools are used, since they may also need the kind of reporting capabilities that PharmaMV RT Manager excels in.

Here at iText, we'll be following these developments with great interest.



## ABOUT PERCEPTIVE ENGINEERING

Perceptive Engineering are an innovative software and solutions company based near Warrington in the UK. They develop software and data-driven solutions for advanced process control in manufacturing across various industries, including pharmaceutical, food & nutrition, paper, and public utilities.

The company was formed in 2003 with a clear mission: to improve the efficiency of complex manufacturing and

treatment processes, using robust and powerful statistical tools, combined with leading-edge academic thinking.

Consisting of a team of experienced control engineers, they are entrusted by companies around the world to meet the manufacturing challenges of the future, using problem-solving skills honed over the years, and their award-winning Advanced Process Control software platform.

We chose iText to power the PDF reporting engine in PharmaMV RT Manager as it could both work with our existing Java-based software, and also be embedded within an application. In addition, iText's ease of use and ability to process the massive amounts of data handled by the RT Manager made it a natural choice.

**ANDY MITCHELL - PRINCIPAL ENGINEER (STRATEGIC PROJECTS), PERCEPTIVE ENGINEERING LIMITED**

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## ABOUT US

iText is a global leader in innovative award-winning PDF software used by millions of users worldwide to create digital documents like invoices, credit card statements, mobile boarding passes, and more. The iText 7 Core library is available as open source, while commercial licensing provides professional support and release from AGPL requirements. The iText 7 Suite includes a wide range of add-ons for extra functionality, and we also develop iText DITO: a low-code, template-based PDF generator.

iText works and works well. Our customers choose iText because of our world-class software quality, and our reliable, mature, and proven technology. Our PDF solutions can be embedded into the document workflows of various industries and their applications to create and manipulate PDFs, tasks like secure content redaction, encryption, digital signatures, and ensuring documents are accessible and archivable.

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