Regulatory Compliant *PI* Batch Reporting

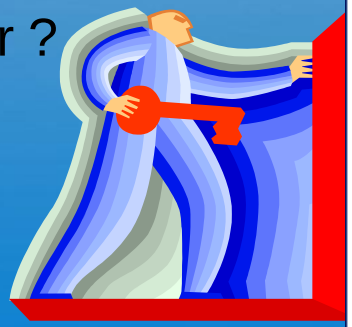
Designing for the PI Application Framework

What is the need ?

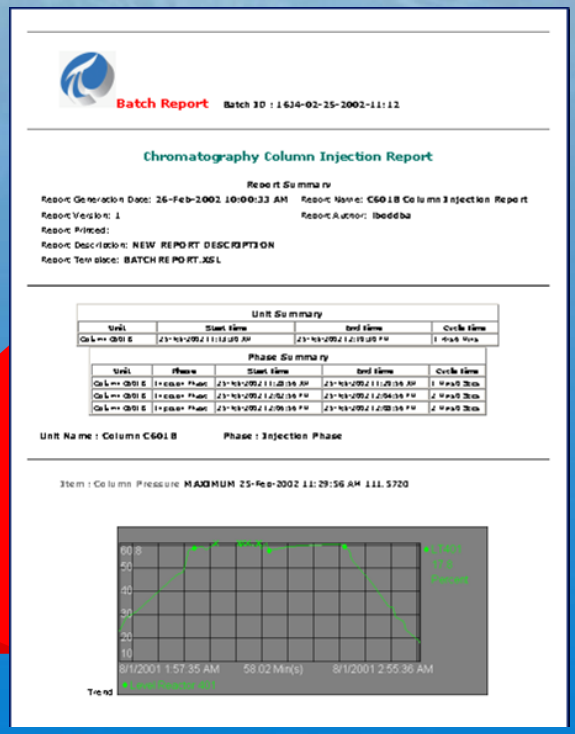
- In 1997 FDA came out with Regulatory Requirement 21 CFR Part 11 – Electronic Records and Signatures.

- With historians so far the emphasis has been on the ability to store Electronic Records in a secure and auditable manner.

- But the data is now in a secure ‘locked box’. So how can you create batch reports in a compliant manner ?



OSI is now focused on using PI’s power to provide compliant reports out of the ‘locked box’ !


Batch Report Batch ID : 1634-02-25-2002-11:12

Chromatography Column Injection Report

Report Summary

Report Generation Date: 26-Feb-2002 10:00:33 AM Report Name: C601B Column Injection Report

Report Version: 1 Report Author: lbeddba

Report Printed:

Report Description: NEW REPORT DESCRIPTION

Report Template: BATCH REPORT.XSL

Unit Summary

Unit	Start Time	End Time	Cycle time
Column C601B	25-Feb-2002 11:12:35 AM	25-Feb-2002 12:29:35 PM	1 Hour 17m

Phase Summary

Unit	Phase	Start Time	End Time	Cycle Time
Column C601B	1 Injection Phase	25-Feb-2002 11:28:36 AM	25-Feb-2002 11:29:56 AM	1 Hour 20m
Column C601B	1 Injection Phase	25-Feb-2002 12:02:36 PM	25-Feb-2002 12:04:36 PM	2 Hour 0m
Column C601B	1 Injection Phase	25-Feb-2002 12:06:36 PM	25-Feb-2002 12:08:36 PM	2 Hour 0m

Unit Name : Column C601B Phase : Injection Phase

Item : Column Pressure MAXIMUM 25-Feb-2002 11:29:56 AM 111.5720

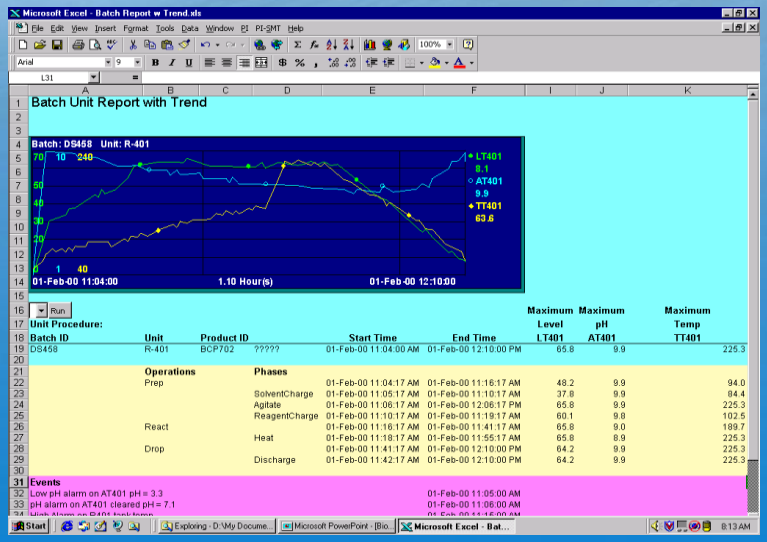
60.8
50
40
30
20
10
8/1/2001 1:57:35 AM 58.02 Min(s) 8/1/2001 2:55:36 AM

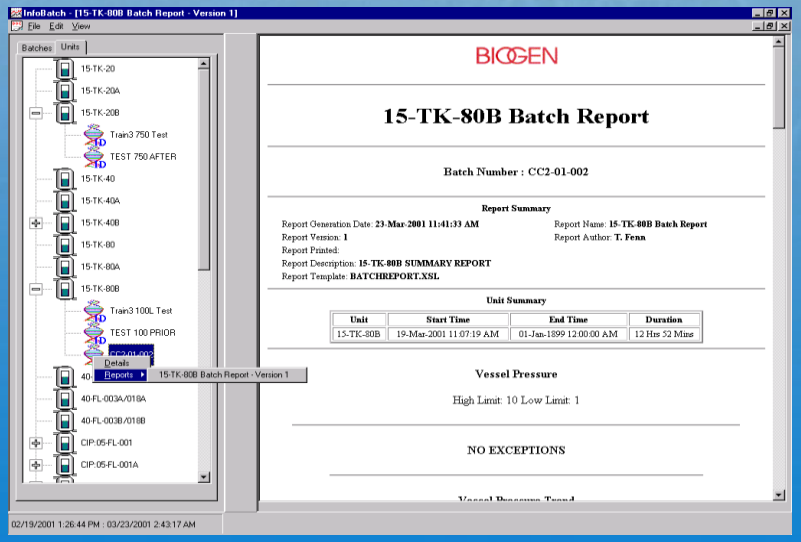
Trend

PI Tools vs. *PI* Applications

- Broad functionality
- Cross-industry
- No versioning, audit trails
- Unstructured configuration
- User-maintained applications
- Intended for engineering use

- Specific functionality
- Industry-focused
- Integrated security
- Strict configuration control
- Strict version control
- Intended for production use





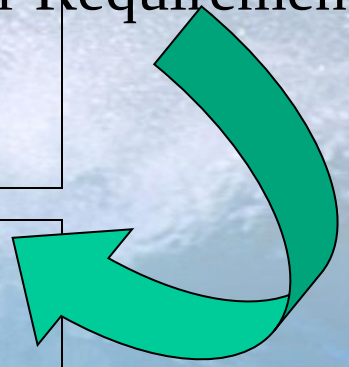
Build it and They will Come !!

- It needs to be a fully configurable *PI* batch reporting product.
- Must fully integrate current *PI* automation functionality
  - use the PI MDb, PI API, PI SDK and PBook automation
- It must produce *PI* batch reports without programming:
  - Production Summaries, Exception Reports …..
  - Detailed Batch Activity, Equipment Preparation …..
- Initially targeted at FDA 21 CFR Part 11 reporting compliance using *PI*
- Version 1 has been operational with Biogen since Jan 01.
- Share our plans and design for the *PI* Application Framework

Customer Batch Report for 750 L Bioreactor

1st Establish

User Requirements



Batch Summary

Batch Number:	PI_TEST20A
Product:	Test Product
Batch Started:	Tuesday, March 28, 2000 1:45 PM
Batch Ended:	Tuesday, March 28, 2000 5:35 PM
Batch Duration:	3 hours 50 minutes

Report Summary

Report Print Date:	Thursday, April 19, 2000 4:30 PM
Report Name:	Batch Excursion Report for Bioreactors
Report Version:	Version 1.0
Report Author:	A J Fenn
Report Description:	Used to flag any exceptions from normal limits
Report Template:	ReportServer/C:/Reports/Simple Batch Report.rpt
Report Printed:	

Excursion Summary

750 LBioreactor 15-TK-20A

Tag Name	Limits	Phase	
Vessel Pressure (psig)	**Lower:1 Upper:10**	**Heating**	
	Low: March 28, 2000 1:47 PM		0.0
Vessel Temperature (deg.C)	**Lower:34.5 Upper:36.5**	**Heating**	
	High: March 28, 2000 1:48 PM		37.2
Agitator Speed (RPM)	**Lower:20 Upper:40**	**Heating**	
	Low: March 28, 2000 1:57 PM		0.0

{etc.}

Process Step Excursion Details

Step Name	Step Start	Step End
Heating 2:10 PM	March 28, 2000 1:45 PM	March 28, 2000

Vessel Pressure (psig) — **Lower Limit : 1** — **Upper Limit: 10**

Low :	March 28, 2000 1:47 PM	0.0
Return to Normal:	March 28, 2000 1:55 PM	

{low limit violation, with return to normal action}

Vessel Temperature (deg. C) — **Lower Limit : 34.5** — **Upper Limit: 36.5**

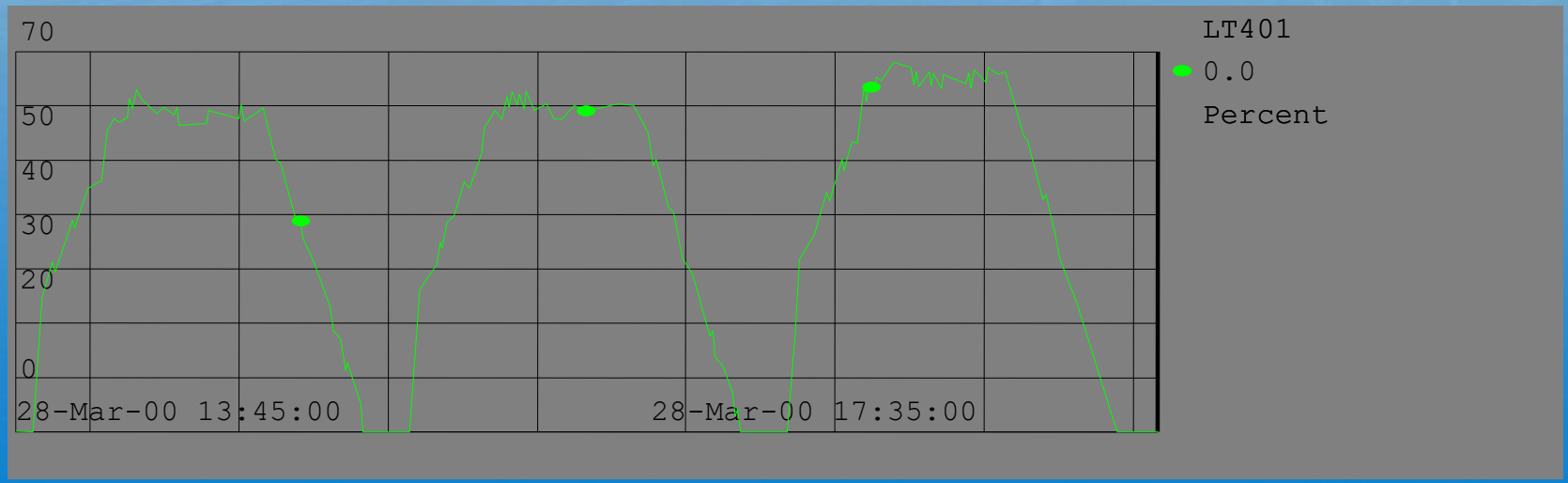
High :	March 28, 2000 1:48 PM	37.2
Dissolved Oxygen (%pO2):		34.3

{hi limit violation, with log other tag action}

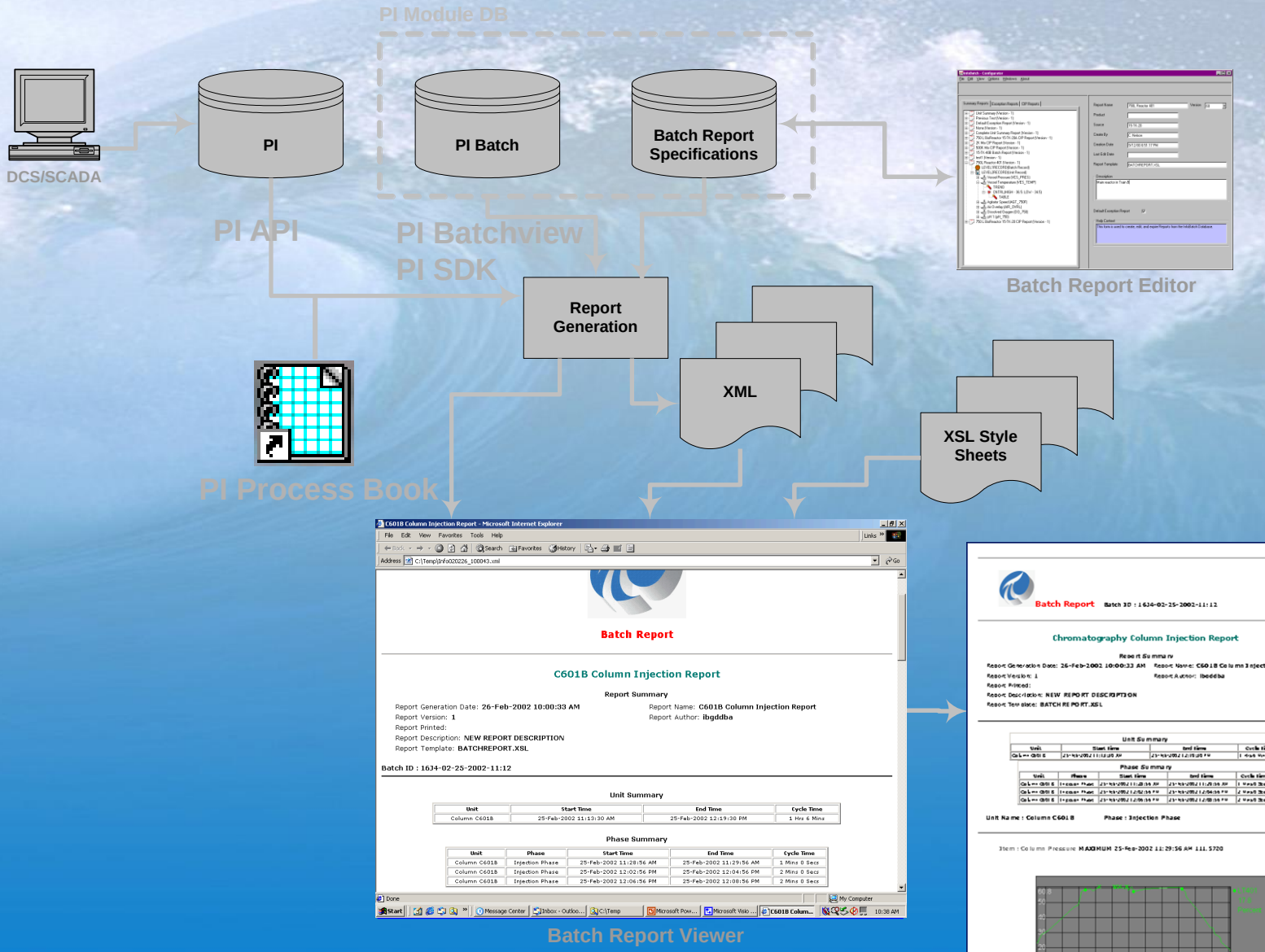
Agitator Speed (RPM) — **Lower Limit : 20** — **Upper Limit: 40**

Low :	March 28, 2000 1:57 PM	0.0

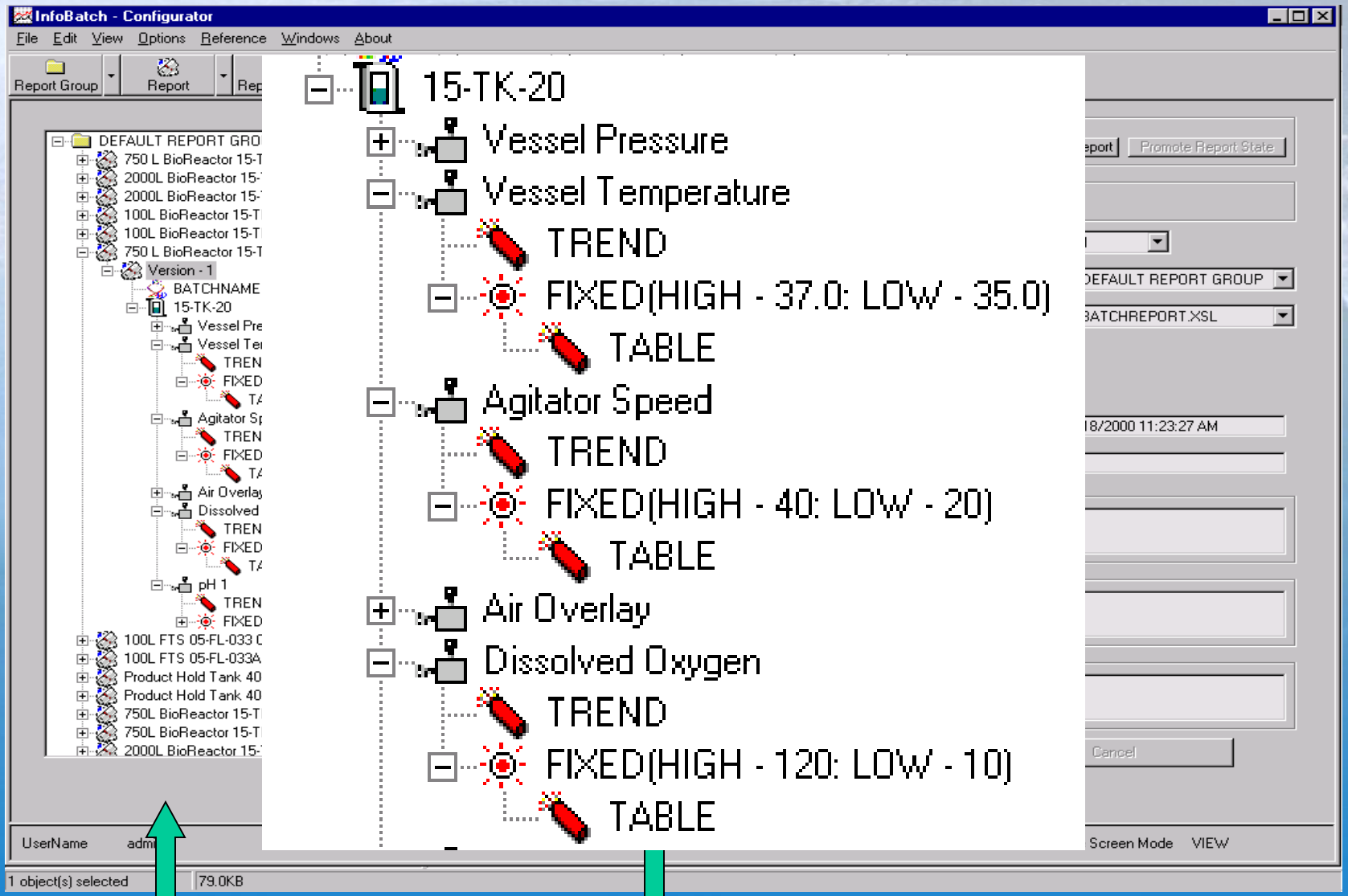
Trend: Agitator Speed (RPM)



So how do you currently do this with PI 3.3 ?

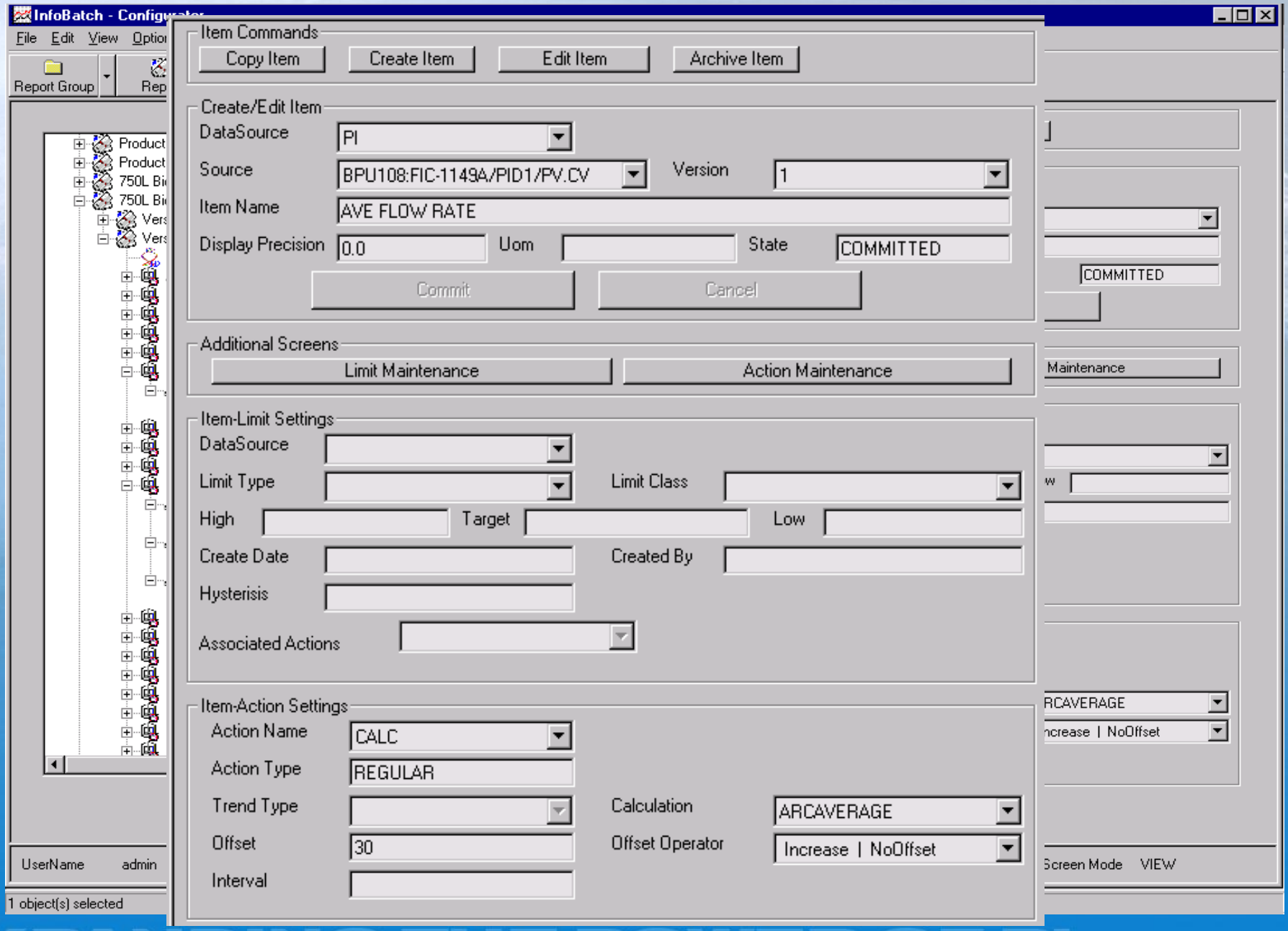


Batch Report Editor - report building - versioning - tag/limits/actions - release



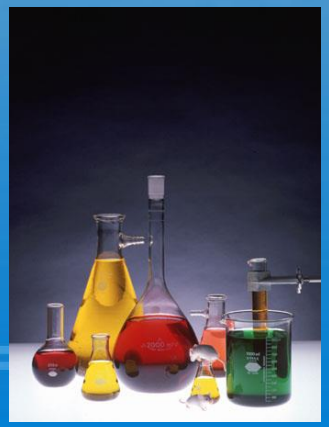
Report Explorer

Report Specifications

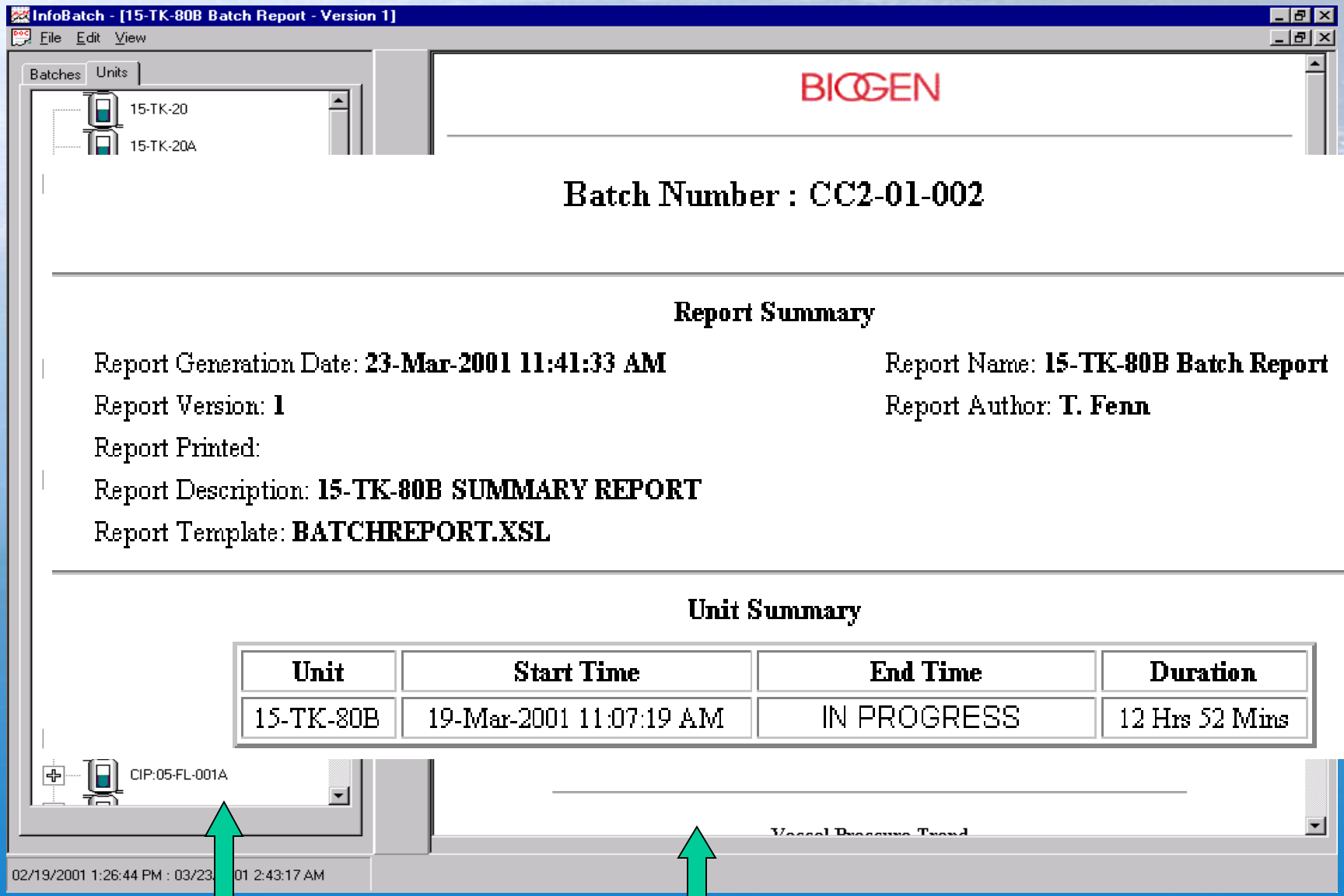

InfoBatch - Configurator
File Edit View Optio
Report Group
Rep
Product
Product
750L Bi
750L Bi
Vers
Vers
UserName admin
1 object(s) selected
Item Commands
Copy Item
Create Item
Edit Item
Archive Item
Create/Edit Item
DataSource PI
Source BPU108:FIC-1149A/PID1/PV.CV
Version 1
Item Name AVE FLOW RATE
Display Precision 0.0
Uom
State COMMITTED
Commit
Cancel
Additional Screens
Limit Maintenance
Action Maintenance
Item-Limit Settings
DataSource
Limit Type
Limit Class
High
Target
Low
Create Date
Created By
Hysterisis
Associated Actions
Item-Action Settings
Action Name CALC
Action Type REGULAR
Trend Type
Calculation ARCAVERAGE
Offset 30
Offset Operator Increase | NoOffset
Interval
COMMITTED
Maintenance
RCAVERAGE
ncrease | NoOffset
Screen Mode VIEW

Highlights of Report Editor

- **Supports PI Module Db**
- Multi level reports
  - Batch, unitop, operation procedure, phase etc…
  - Additional hierarchies
- Copy/Cut/Paste
- Automatic versioning and auditing
- Intelligent pop up menus
- Intelligent use of PI data
- Tag string parsing
- Tag groupings
- Detailed administration functions
  - Multiple Limit types
  - Define product types
  - Registry settings



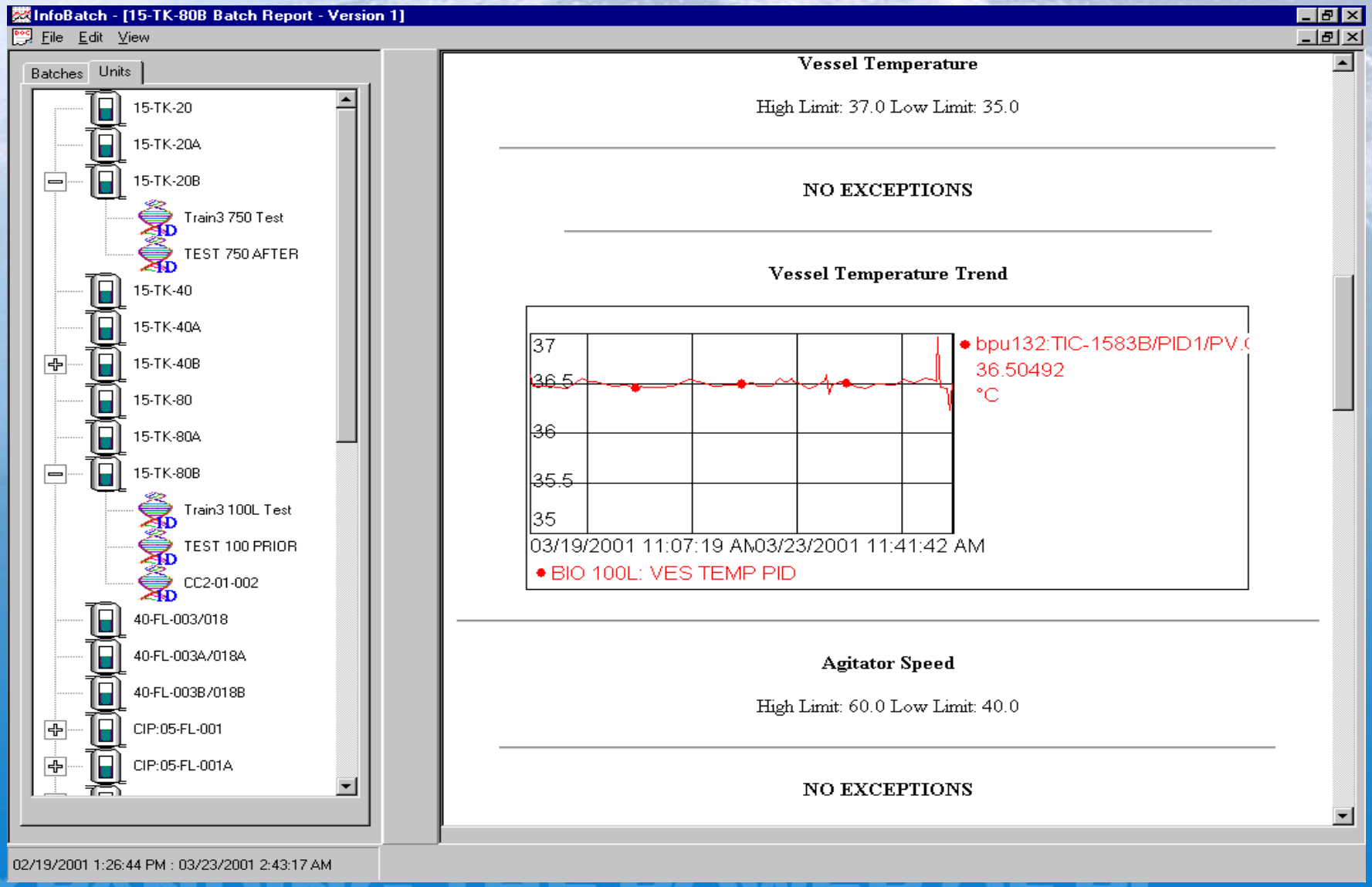
Batch Report Generator - batch . unit . product search - report generation - report print



Batch Explorer

Browser Report Viewer

Exception Report showing embedded trends



Highlights of Report Generator

- **PI Module DB support of batch searching**
- Batch Tree View
- Generate Reports on any SP88 level
- Protected trends
- Multiple tags on trends

- Additional security of embedded Explorer
- Printout only allowed
- Auto pagination of report printouts
- XSL Style sheets embedded in executable
- Deletion of temporary files

Why Application Framework?

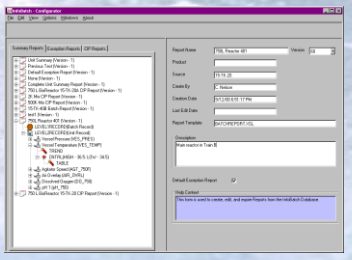
- Infrastructure, Infrastructure, Infrastructure
  - Elements (Equipment)
  - Operating Environment
  - Extensible
  - Components
  - Tighter Application Integration

PI Application Framework Server

DCS/SCADA

PI

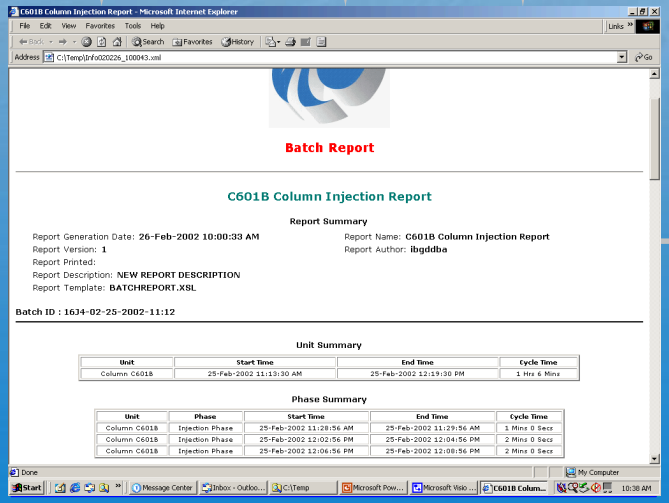
PI AF PLUG INS



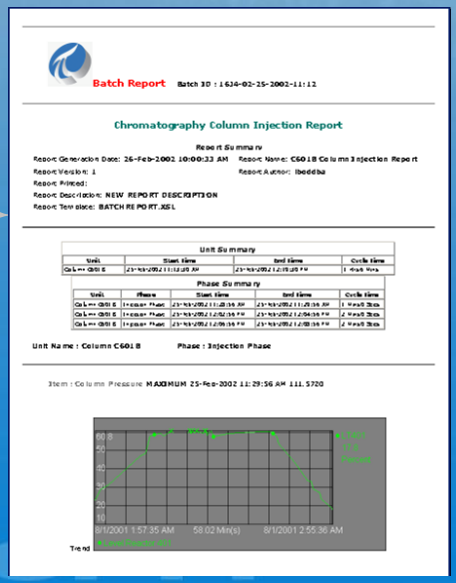
Batch Report Editor

XML

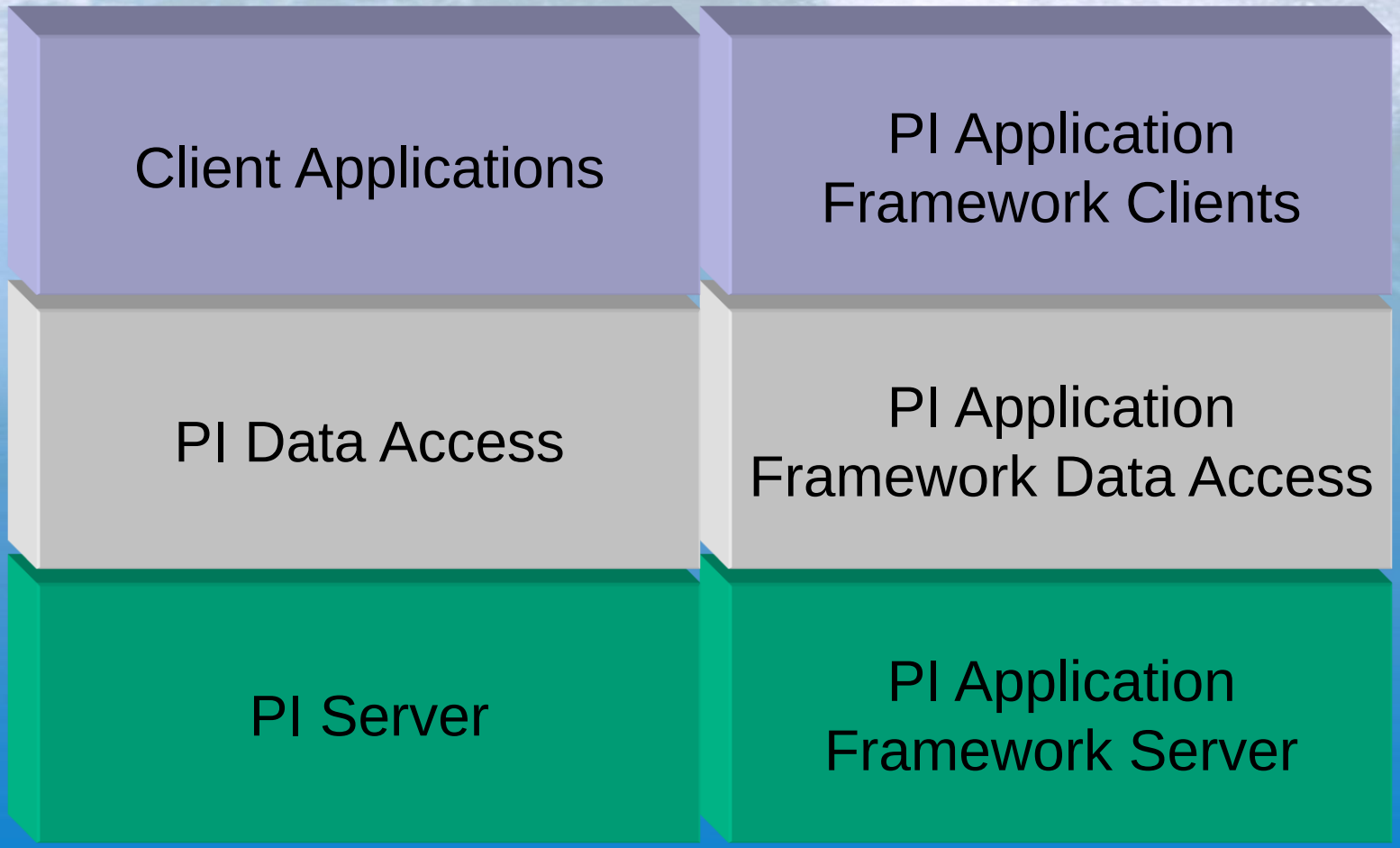
XSL Style Sheets

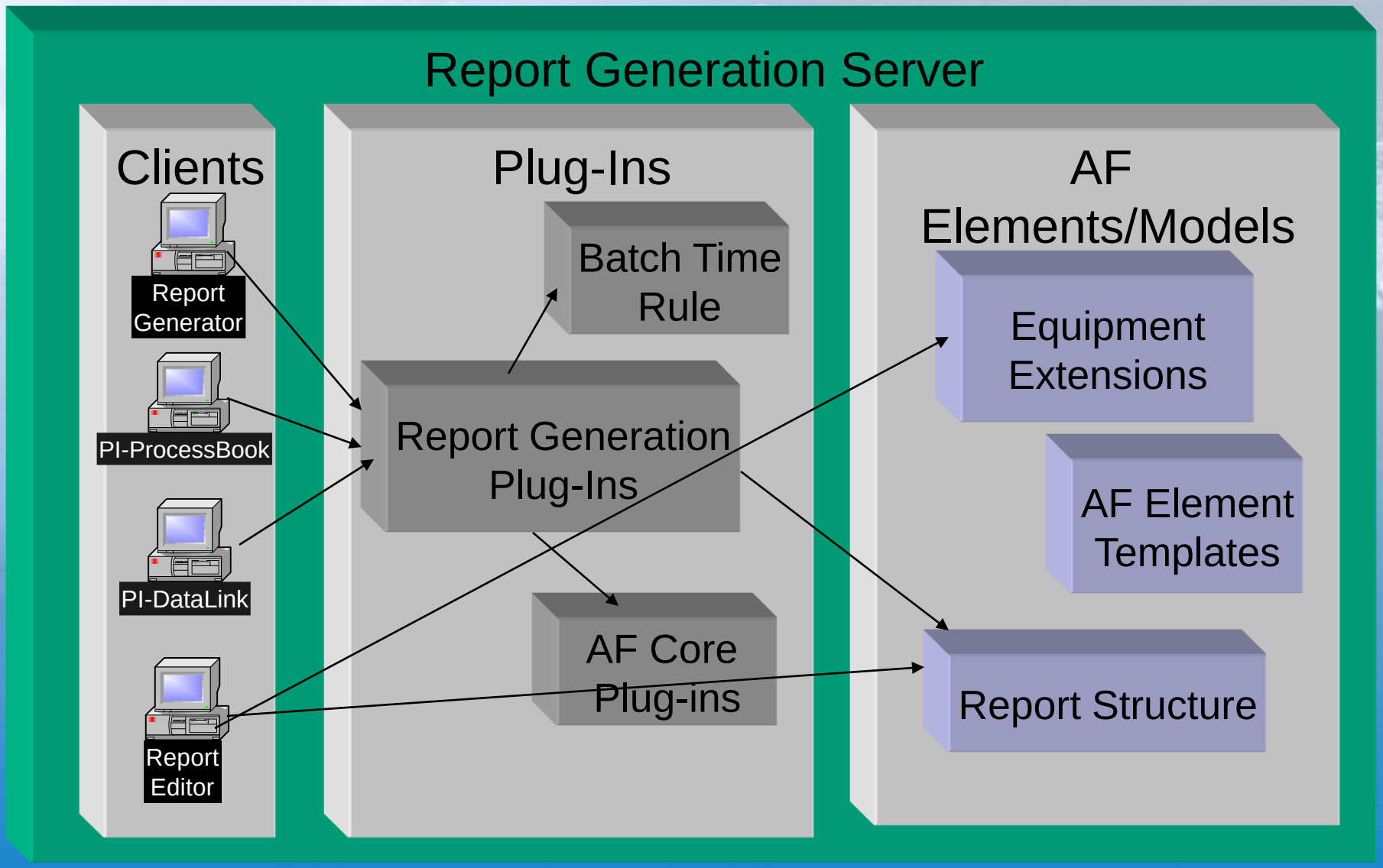


Batch Report Viewer



PI Application Framework




Report Generation Server
Clients
Report Generator
PI-ProcessBook
PI-DataLink
Report Editor
Plug-Ins
Batch Time Rule
Report Generation Plug-Ins
AF Core Plug-ins
AF Elements/Models
Equipment Extensions
AF Element Templates
Report Structure

Element/Models

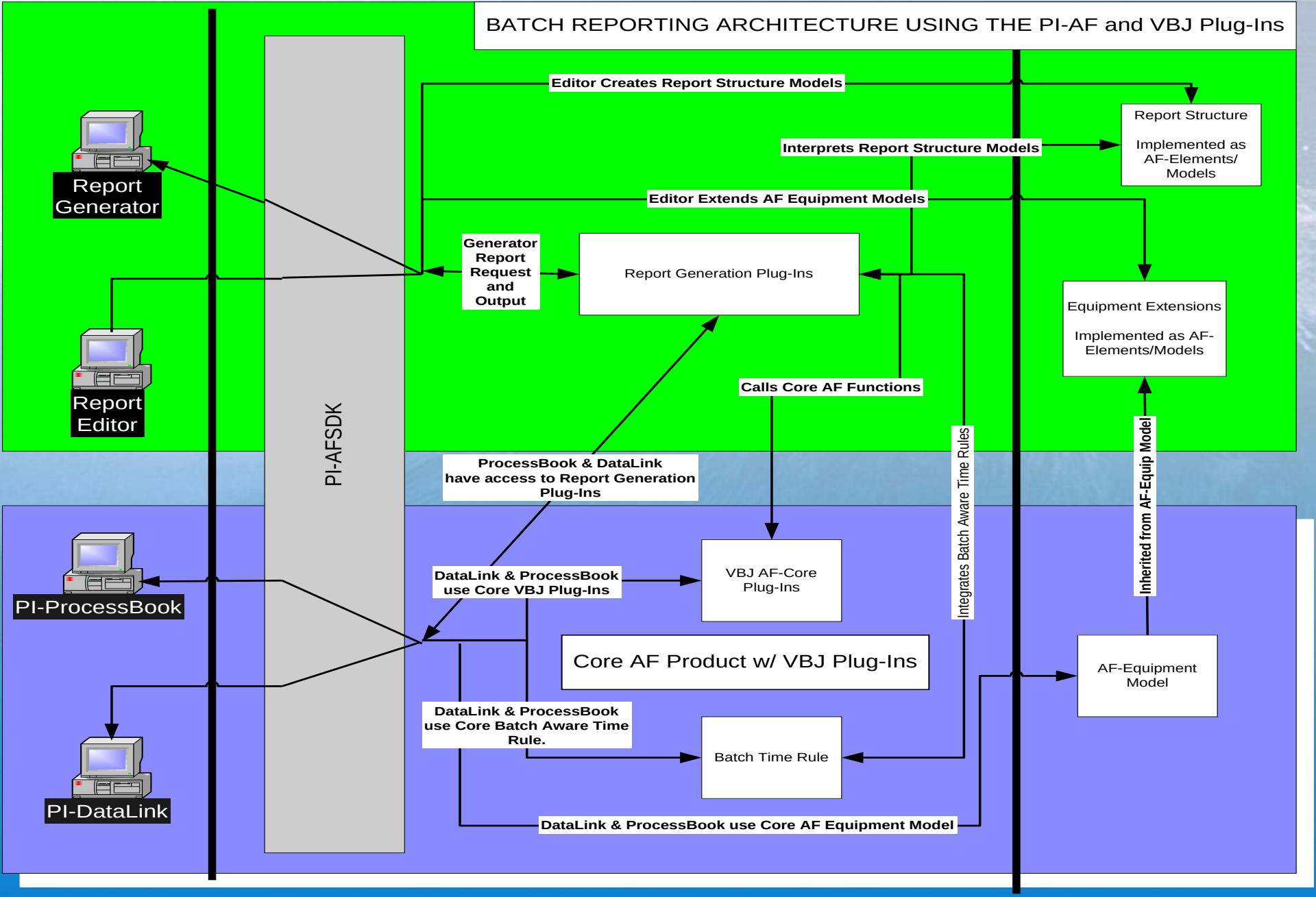
- Equipment Extensions
  - Specific Equipment Usage
  - Product Type
- Report Structure
  - Report Summary Information
  - Report Section Information
  - Specific Limits and Actions

Plug-Ins

- Batch Time Rule
  - Provide Batch Functionality to Plug-Ins
- Core AF Plug-Ins w/ VBJ Plug-Ins
  - Perform Specific Service, I.e. CheckLimits, Associated Tag Information
- Report Generation Plug-Ins
  - Report Generation Infrastructure
  - Interpret report structure
  - Provide Context information to Core AF Plug-ins

VBJ Plug-Ins

- Process Event Analysis Rules
  - Limit Check
  - Ramping Check
  - State Change Check
  - Event Monitoring
  - Material Charge Information


BATCH REPORTING ARCHITECTURE USING THE PI-AF and VBJ Plug-Ins
Editor Creates Report Structure Models
Report Structure
Implemented as AF-Elements/ Models
Interprets Report Structure Models
Editor Extends AF Equipment Models
Report Generator
Generator Report Request and Output
Report Generation Plug-Ins
Equipment Extensions
Implemented as AF-Elements/Models
Report Editor
PI-AFSDK
Calls Core AF Functions
Integrates Batch Aware Time Rules
Inherited from AF-Equip Model
ProcessBook & DataLink have access to Report Generation Plug-Ins
PI-ProcessBook
DataLink & ProcessBook use Core VBJ Plug-Ins
VBJ AF-Core Plug-Ins
Core AF Product w/ VBJ Plug-Ins
AF-Equipment Model
DataLink & ProcessBook use Core Batch Aware Time Rule.
Batch Time Rule
PI-DataLink
DataLink & ProcessBook use Core AF Equipment Model

Benefits And Future Functionality

- Types of Report
  - Equipment Based Reporting
  - Procedure Based Reporting
  - Standard Reports (Shift, Daily, etc.)
- Future Functionality
  - Report Output/Export
  - Report Approval Process
  - Report Verification
  - Integration w/ ICE