RtReports: A Bristol-Myers Squibb Perspective
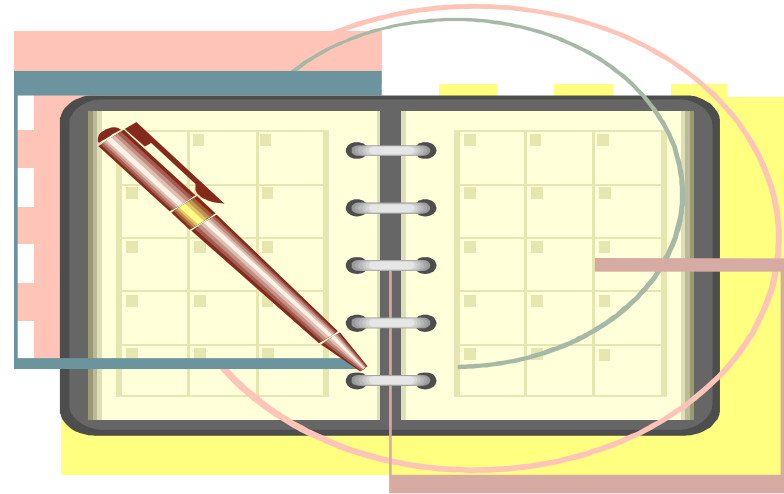
Presented by **Anthony Valbrun**

Bristol-Myers Squibb

- Bristol-Myers Squibb is a global BioPharma company firmly focused on its Mission to discover, develop and deliver innovative medicines that help patients prevail over serious diseases.

Key Facts	
Chief Executive Officer	Lamberto Andreotti
Headquarters:	New York City
Business	Biopharmaceuticals
Web Address	www.bms.com
NYSE Listing	BMY
Net Sales	$17.6 billion in 2012
R&D Investment	$3.9 billion in 2012
Key Products	ABILIFY® (aripiprazole), ATRIPLA® (efavirenz / emtricitabine / tenofovir disoproxil fumarate), BARACLUDE® (entecavir), ELIQUIS® (apixaban), ERBITUX® (cetuximab), IXEMPRA® (ixabepilone), KOMBIGLYZE™ (saxagliptin and metformin), NULOJIX® (belatacept), ORENCIA® (abatacept), ONGLYZA® (saxagliptin), PLAVIX® (clopidogrel bisulfate), REYATAZ® (atazanavir sulfate), SPRYCEL® (dasatinib), SUSTIVA® (efavirenz), YERVOY® (ipilimumab)

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Agenda

- Implementation History
- Benefits
- Pain Points
- Opportunities

Our Challenges Before RtReports

- QA reviewed batch records in the control room
- Hundreds of records were unnecessarily reviewed
- Information was transcribed many times
- QA needed an electronic tool for reviewing the batch records remotely

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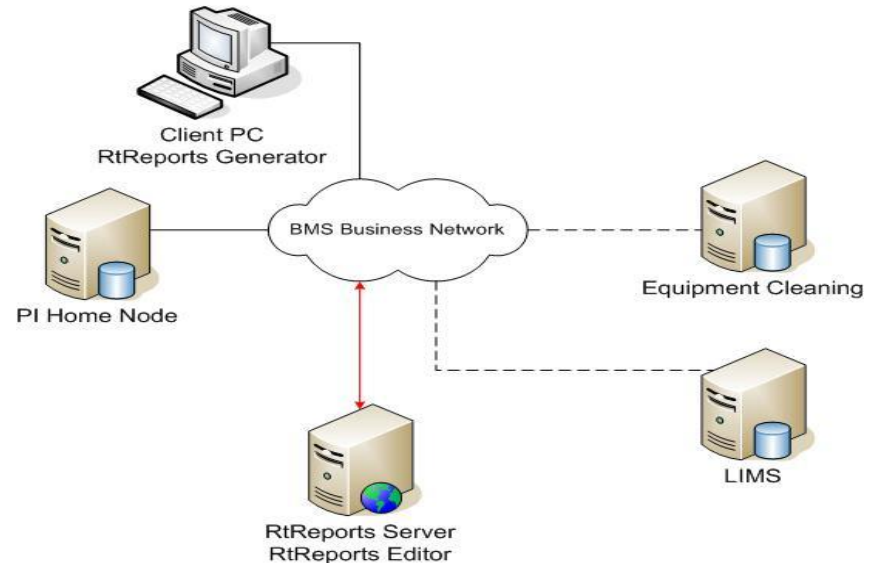
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OSIsoft to the Rescue

- RtReports Early adopter program
- Project took two years for implementation
- Multiple challenges were overcome
  - PI Interface for Event File data
- System implemented in 2004

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Current State

- Critical piece of our operations
- Used across six pilot plants and clinical manufacturing
  - Recently implemented at one of our manufacturing site in Cruiserath, Ireland
- Reporting on both PI System data and external data sources
- Running version 3.3

Benefits

- Review time performance increase
  - Batch review time down 80%
  - Only review relevant information
  - About 10% of the batch records produced
  - Eliminate documentation errors
  - No more transcription
  - No more chasing signatures
  - One stop shopping for batch related data (LIMS, Equipment Cleaning, etc)
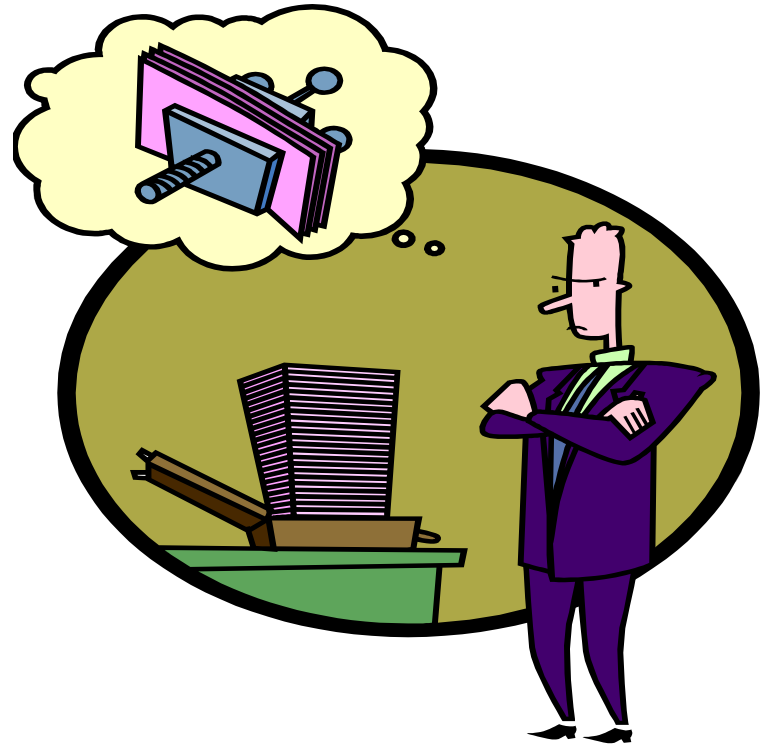
Flexibility

- Ability to have data streaming live
- Pull information while batching
- Accessible from home
- Flexible template used across six pilot plants

Cultural change

- From batch report to Executed batch end review
- 100 pages down from ~700 pages
- Summarized the exceptions that QA needs to review in the first 10 pages
- Exception based batch level approval
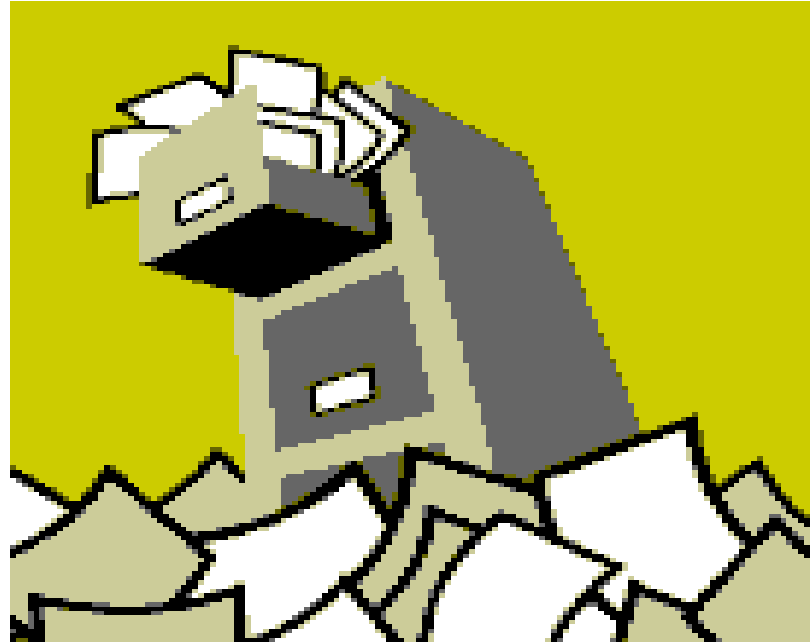- QA helps design the template

Pain Points

- Performance
  - Considerable amount of time for report page to load
  - Reports takes a long time to generate
  - Impacts workflow for some reviews
  - Forced logoff is a nuisance
- Printing crash frequently
  - Needs to kill acrobat and Microsoft Word on RtReports server
  - PDF printing configuration very complex

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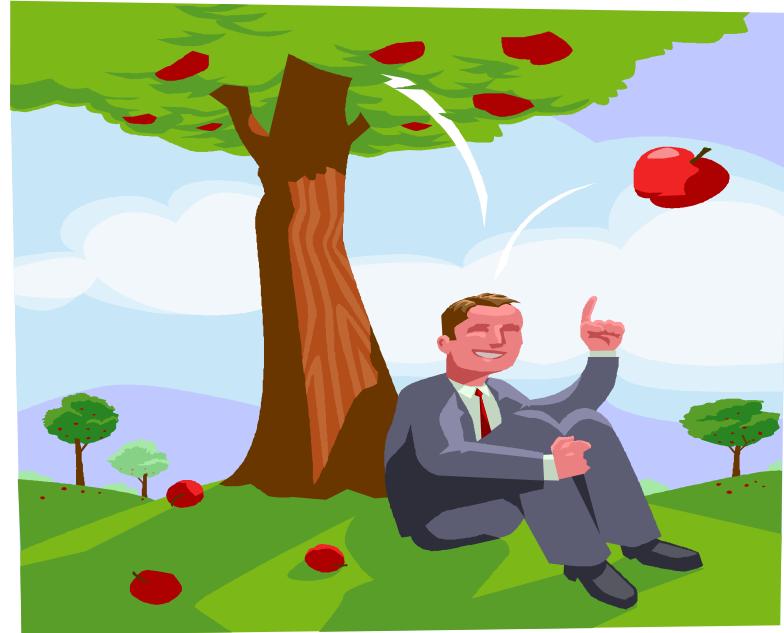Making it easier to
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Pain Points (cont)

- Cache Management
  - Big reports clog up cache
  - Manual flush of cache is often necessary
    - Specially to update external data
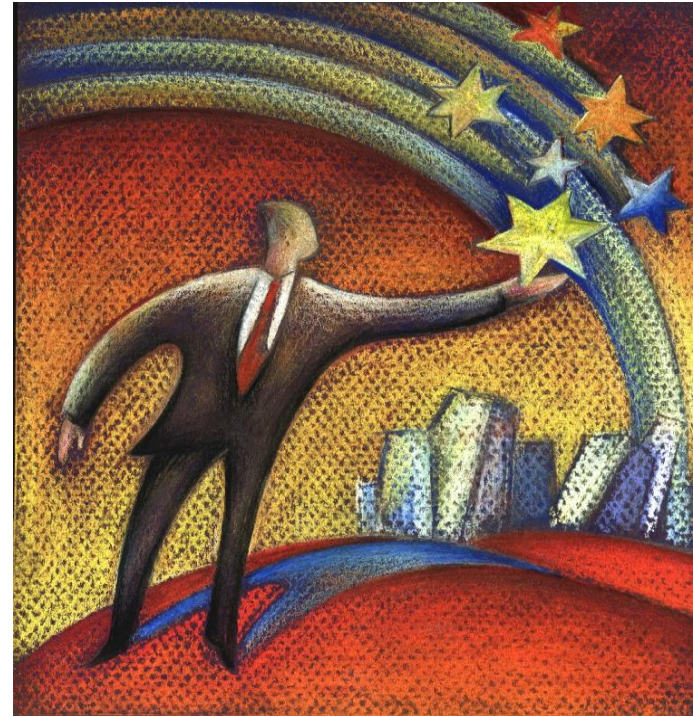- Steep learning curve for template development

Low Hanging Fruits Opportunities

- Data export
- Ability to download journal data to other tools such as Excel, Matlab or a web service
- Email notifications for next level of approval
- Reports generation scheduling
- Optional signature
- Reject a batch
- Access to RtReports metadata for metrics
  - Approval time/reviewers/Etc

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Reaching for the Stars

- RtReports Campaign aware
- Multiple batch summary report
- Ad hoc reporting capability for a nimble pharmaceutical industry
- Contextual comments
  - Ability to add targeted comments to a specific paragraph
- Draft comments workflow

Optimal template

- PI Event Frames ready
- Smooth integration with PI Interface for Emerson DeltaV
- Report phase parameter events in time-order rather than grouping by parameter name
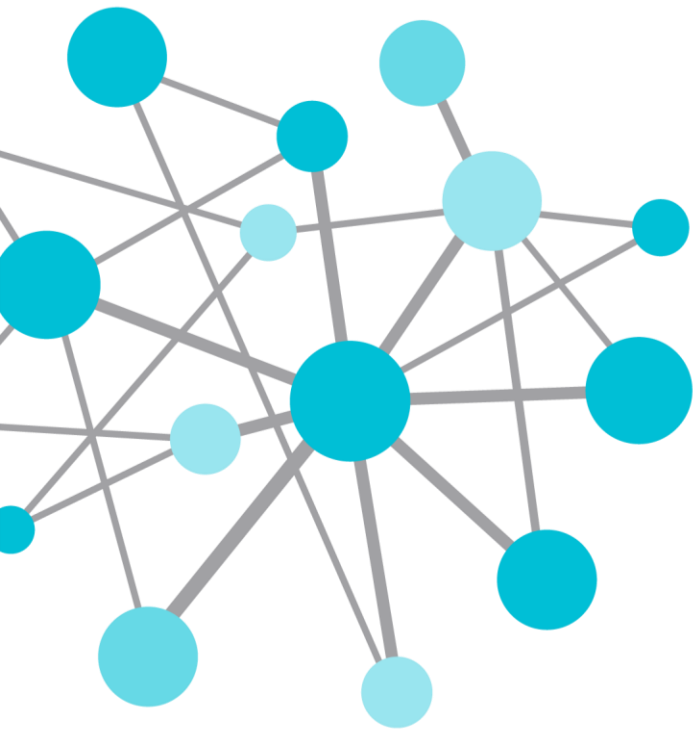
Commitment

- RtReports is BMS official batch end review application
  - Early adopter
  - Big investment
  - Critical to our operation
- Continued partnership with OSIsoft to enhance the product

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RtReports Overview – backup slide

- Template-Based Enterprise Reporting System
- Produces configurable and repeatable reports without programming
- Stores the templates centrally
- Uses a web-based interface
- Provides reports for real-time and historical data
- Provides reports for batches, time ranges or PI Asset Framework (PI AF) cases
- Provides access to PI System data and external data such as relational databases and web services
- Meets sign-off and auditing requirements for electronic reports

THANK YOU

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