Creating a PI Enterprise Historian for AstraZeneca

The OSIsoft Virtual Industry Summits Life Science Summit

Presenter: Joseph A. Hofmann, Jr. PhD, DTM *joe.hofmann@astrazeneca.net*

Contributors:

Michael S. Shackleford (AZ) *michael.shackleford@astrazeneca.com*

Jeffrey Owen (Automated Results) *jeffowen@automatedresults.com*

Date: 28 October 2020

Personal Background

- Business Analyst in R&D IT at AstraZeneca (11 years)
- QA/QC at Centocor/J&J (9 years)
- Lab QC at Warner Lambert (4 years)
- Consulting – Lab Automation
- Education
  - PhD, MS in Chemistry
  - BS in Physics, Environmental Engineering

Presentation Goals

- Overview of Making Biologics
- Goals & Timeline
- New Architecture
- Validation Approach
- Data Migration

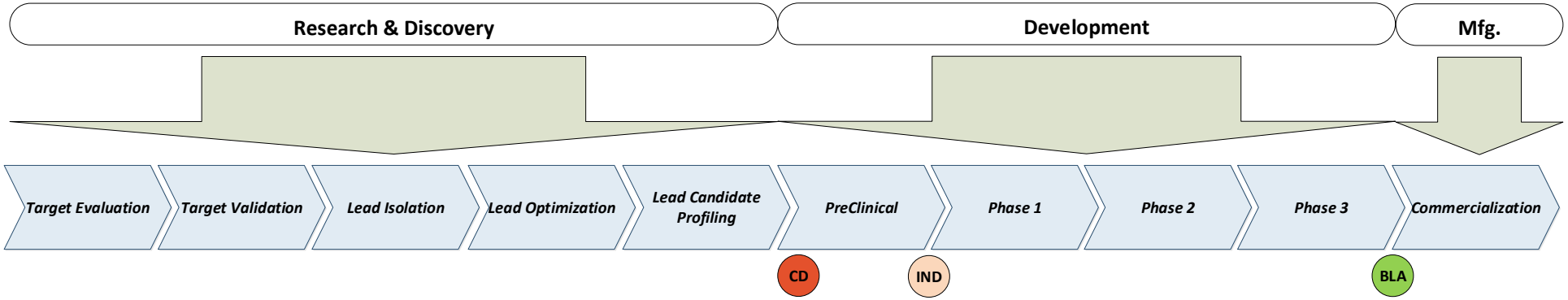
R&D and the Drug Pipeline

Focus of Research is:

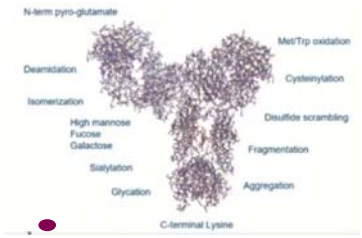
- Biology & Animals
- Discovery of new drug entities/targets

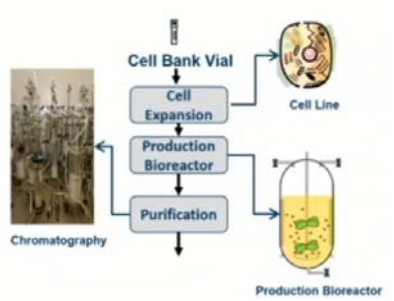
Focus of Development is:

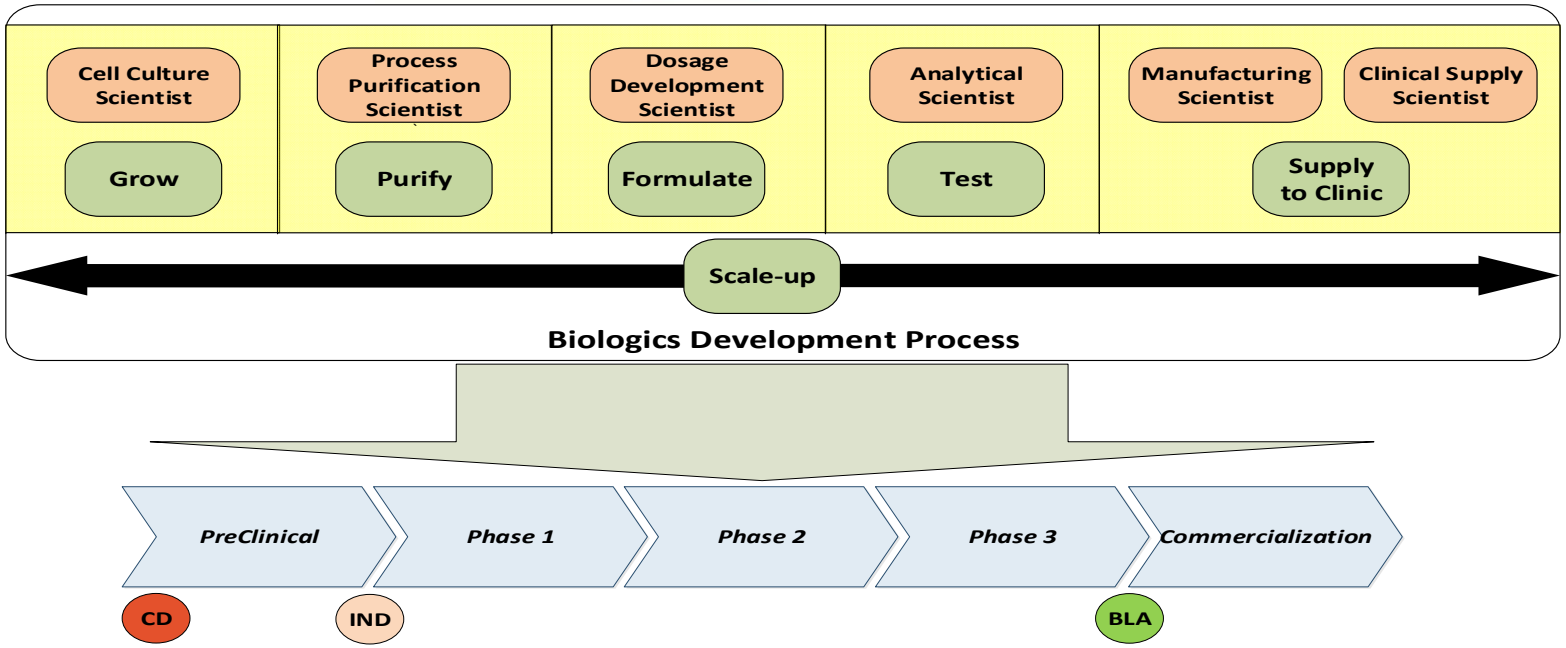
- Scaling the process
- Formulating the product
- Determining how to test the product
- Supplying the product for clinical studies



Biopharmaceutical Development Process





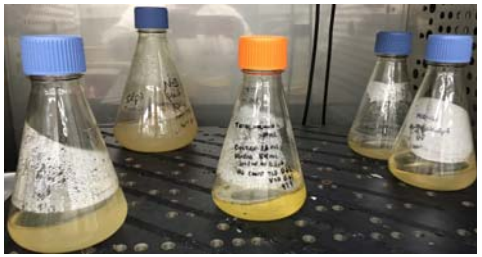


Cell Culture & Fermentation Sciences

Cell Culture Scientist

Grow

96 well plate

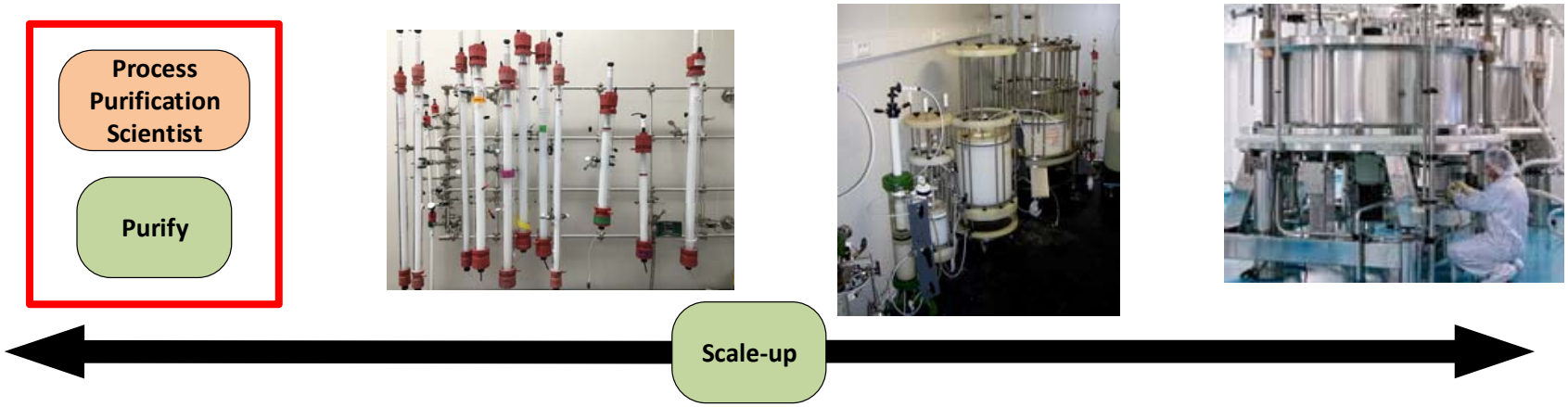


Scale-up

Goals

- Determine best viable cell lines to grow
- Grow cells by most optimum conditions and process
- Scale-up cell fermentation process for clinical studies
- Upstream technology transfer

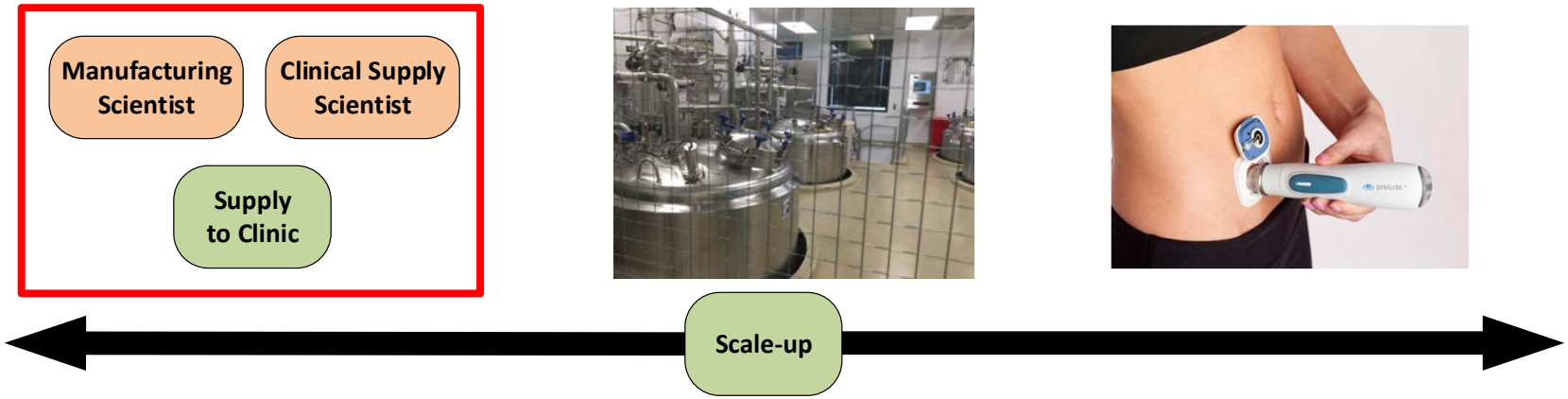
Purification and Process Sciences



Goals

- Determine best conditions to purify Drug Substance
- Purify Drug Substance by most optimum process
- Scale-up Purification process for clinical studies
- Downstream technology transfer

Manufacturing and Supply



Goals - Manufacturing Scientist

- Make drug substance for clinical studies

Goals - Clinical Supply Scientist

- Manage supply of drug substance and drug product during clinical studies
- Forecast demand for drug substance for future studies

Project Goals & Challenges

Mission

- To create a **GMP** enterprise data historian that provides a **secure infrastructure** to control and monitor manufacturing assets while allowing users to **visualize process data and assets** from any AstraZeneca device anywhere in the world.

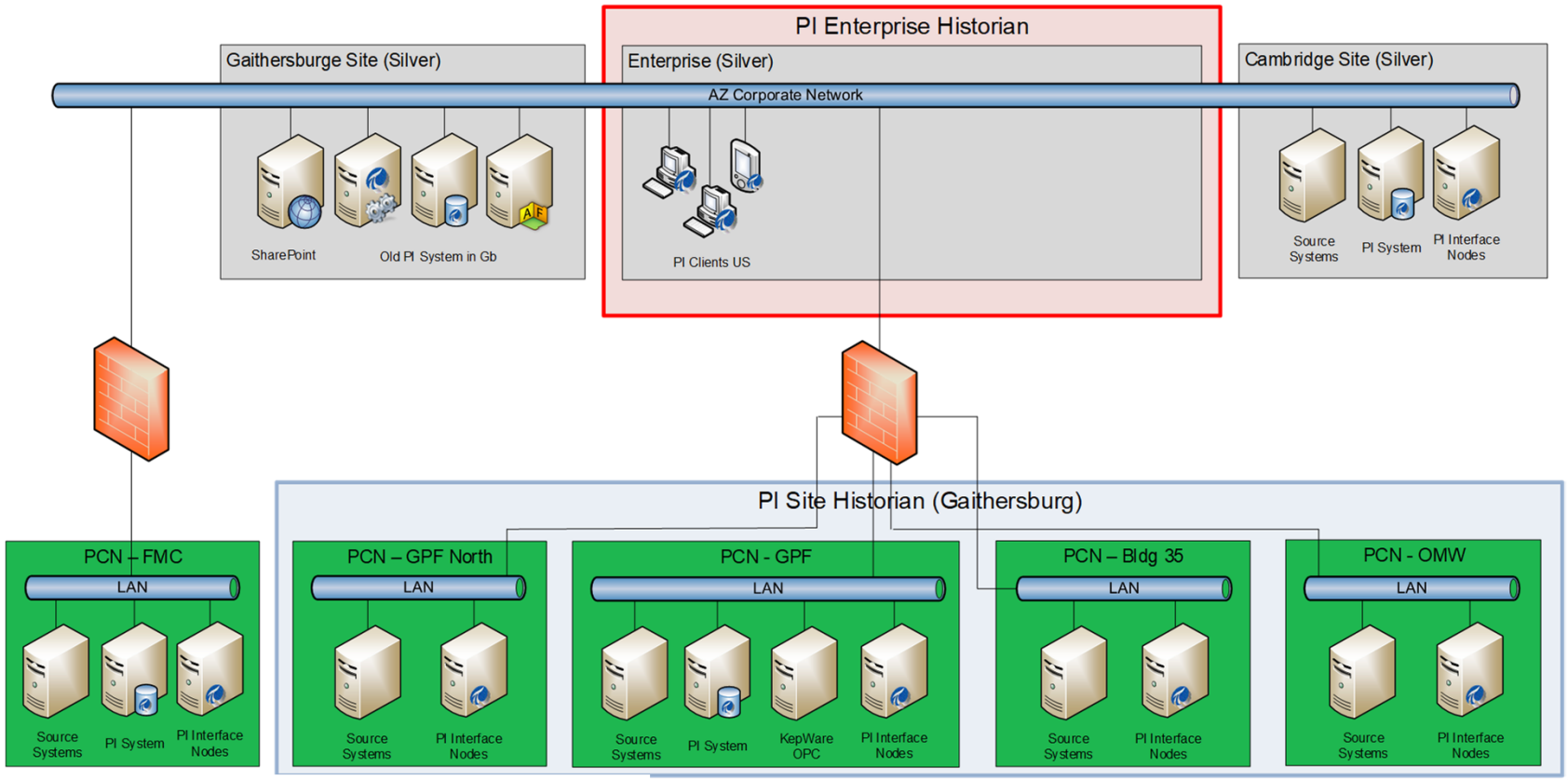
Challenges

- Build PI in a secure infrastructure in the cloud
- Validate the upgraded system in an agile way
- Migrate the data with no down time for the business
- Provide value for the customer

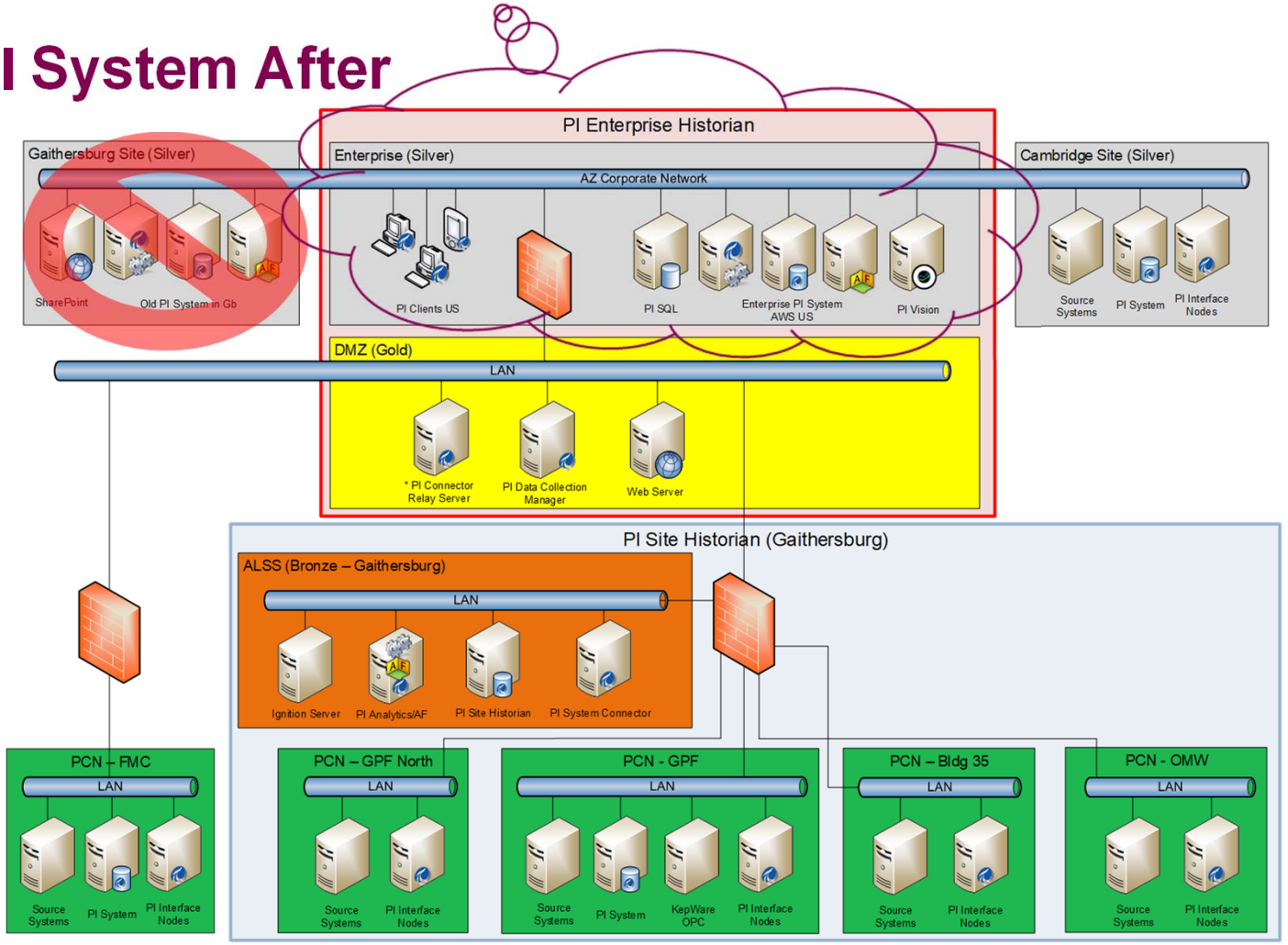
Challenge 1 - Building a Secure Infrastructure

- Upgrade the PI software
- Improve the Infrastructure configuration

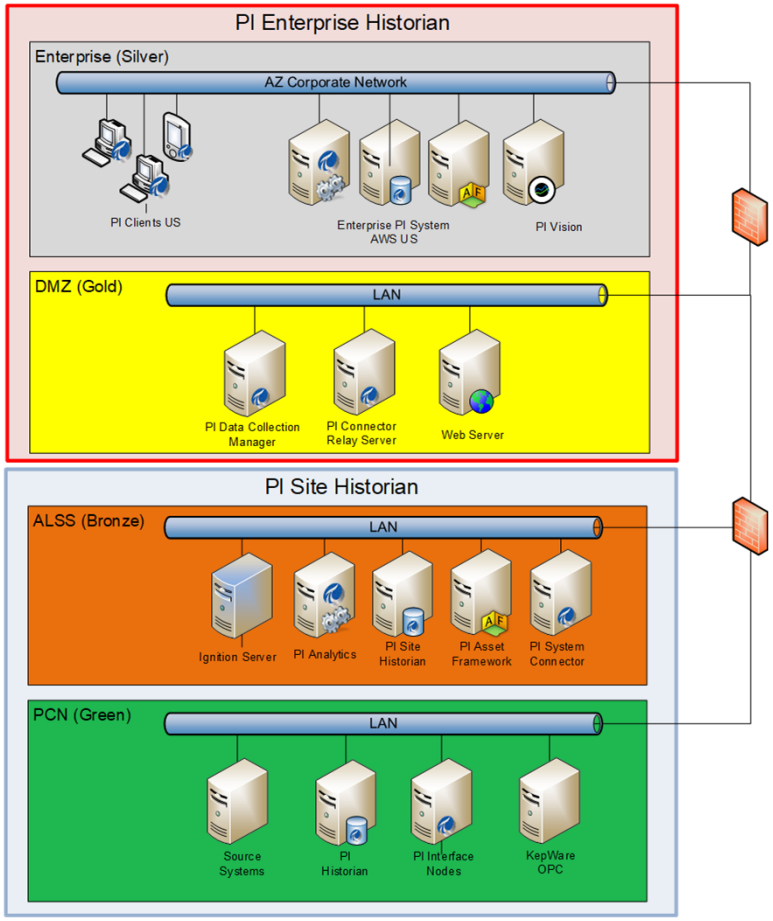
OSI PI System Before



OSI PI System After



Enterprise versus Site Historian

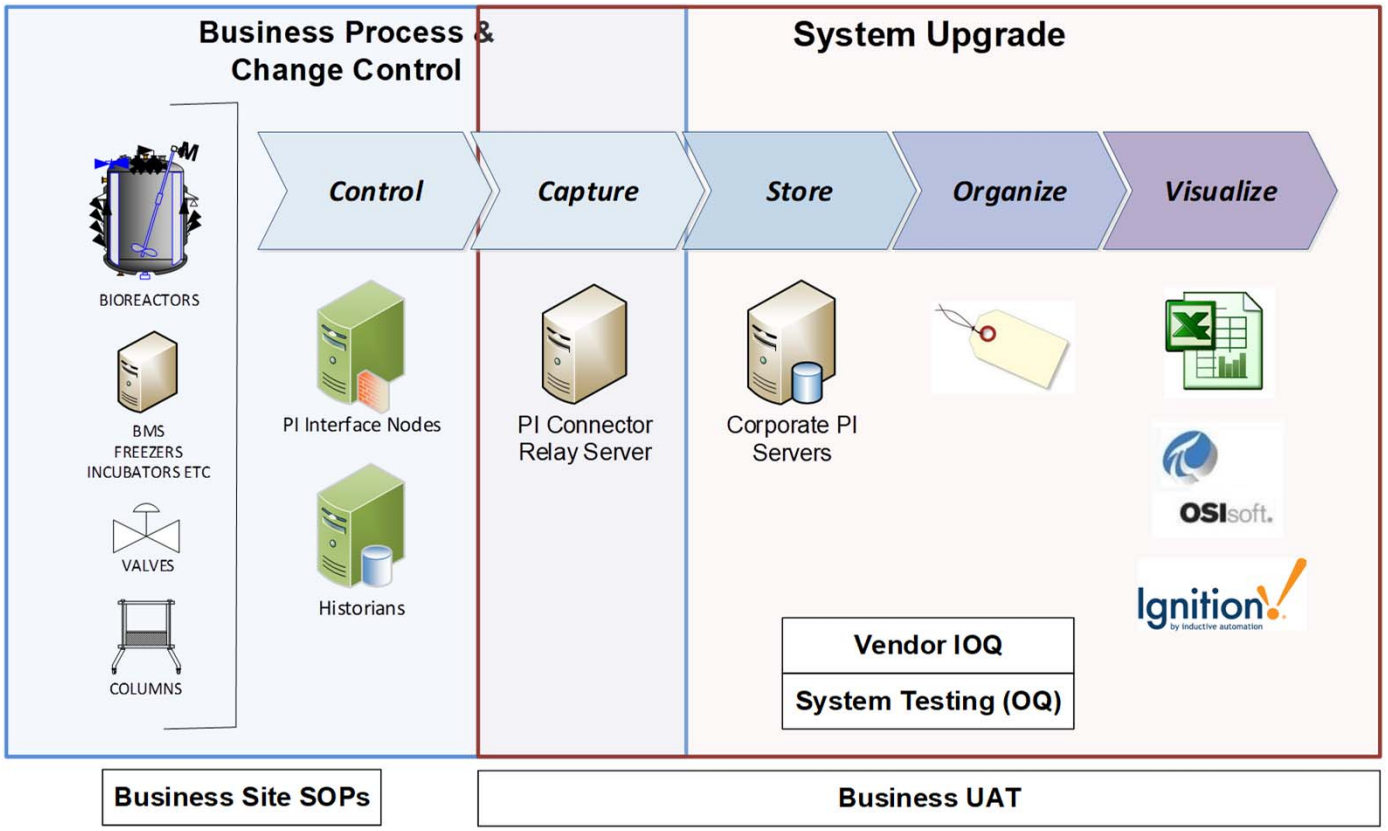


- **Silver Zone**
  - AF Server
  - PI Analytics Server
  - Data Archive Servers (HA)
  - PI Vision
- **Gold Zone**
  - PI Data Collection Manager
  - PI Connector Relay Server
- **Bronze Zone**
  - PI Data Archive Server (HA)
  - AF & Analytics Server
  - PI System Connector Server
- **Green (PCN) Zone**
  - 93 Interface Nodes
  - 3 buildings

Challenge 2 & 3 – Validating the System

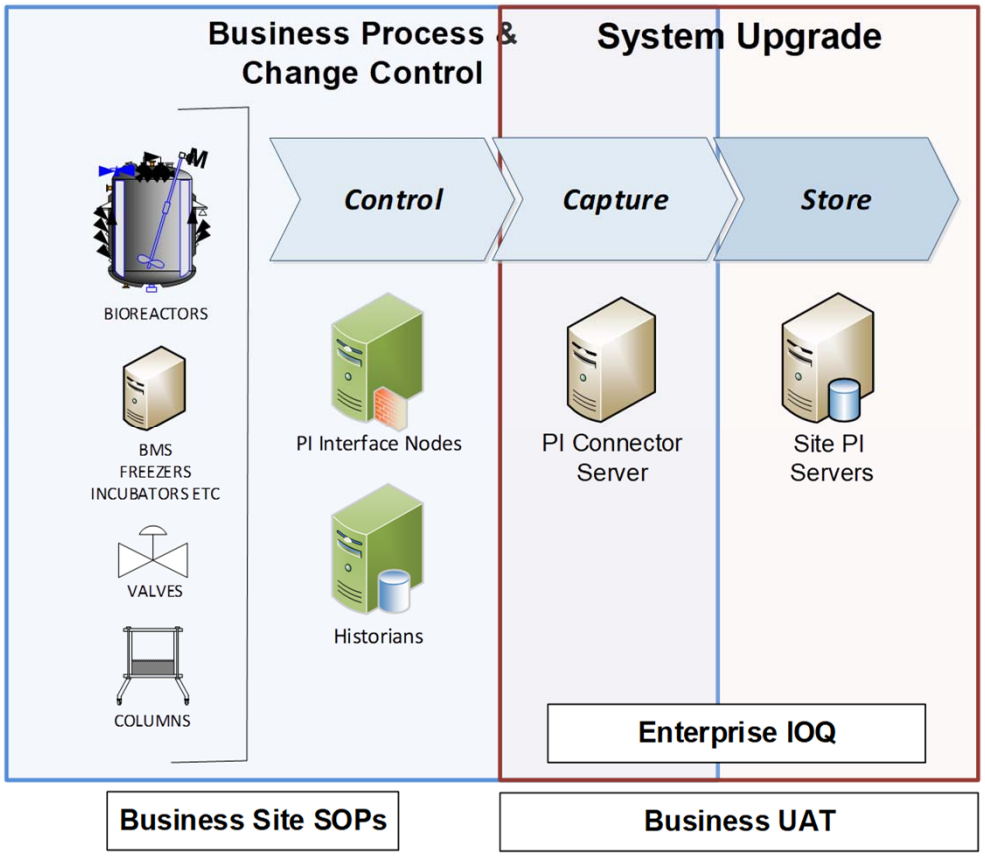
- Splitting the effort into manageable pieces
- Minimize the documentation
- Migrating the data
- Minimize the system down time

PI Enterprise Validation Approach



- Focus on the Enterprise Historian NOT the Site

PI Site Validation Approach



Vendor's Best Practice for Validation

- ✓Qualify the PI Infrastructure NOT the software
- ✓Use OSIsoft's validation templates as a starting point
- ✓Compare to Actual Install and Configuration
- ✓Utilize OSIsoft's on-line training & documentation
- ✓Perform lots of dry runs

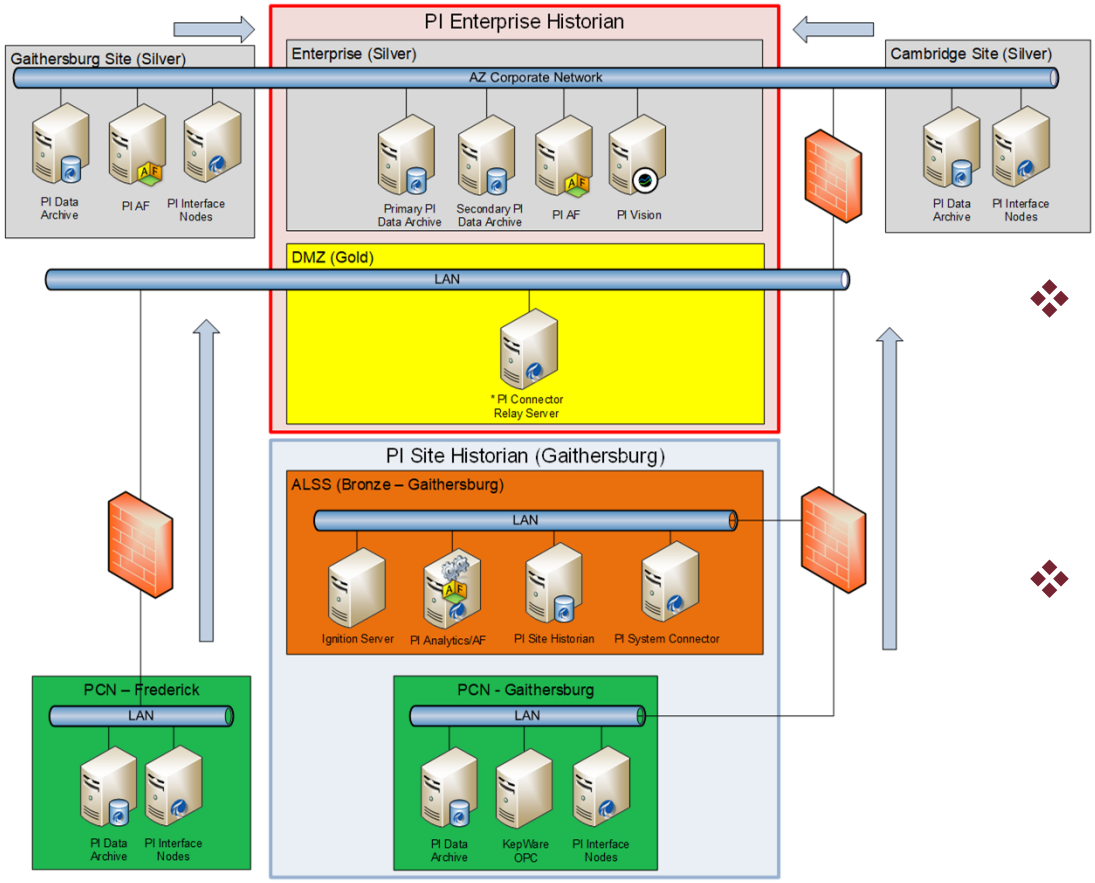
PI Component	RS (FRS/SRS)	DS	IOQ	RTM
PI Data Archive	✓	✓	✓	✓
PI AF Server		✓	✓	
PI Analytics		✓	✓	
PI Vision		✓	✓	
PI Data Collector/Relay		✓	✓	
PI Interface (PI to PI)		✓	✓	
PI Client Tools			✓	

Validation Deliverables

- Created 40 documents for the Enterprise rollout
  - ✓Leveraged the vendor's templates
  - ✓Leveraged across both rollouts wherever possible

Key Document Types	Enterprise Historian	Site Historian
Validation Plan, Test Approach, Migration Plan	3	3
User Requirements	1	
System Requirements (vendor template)	1	
Configuration & Design Specification (vendor templates)	7	1
Solution Blueprint	1	
Test Scripts		
Vendor IQ (vendor install report)	1	1
IOQ (vendor templates)	8	1
User Acceptance Test	1	1
Data Migration	3	
Validation Report, Trace Matrix	2	2

Data Migration – Two Components



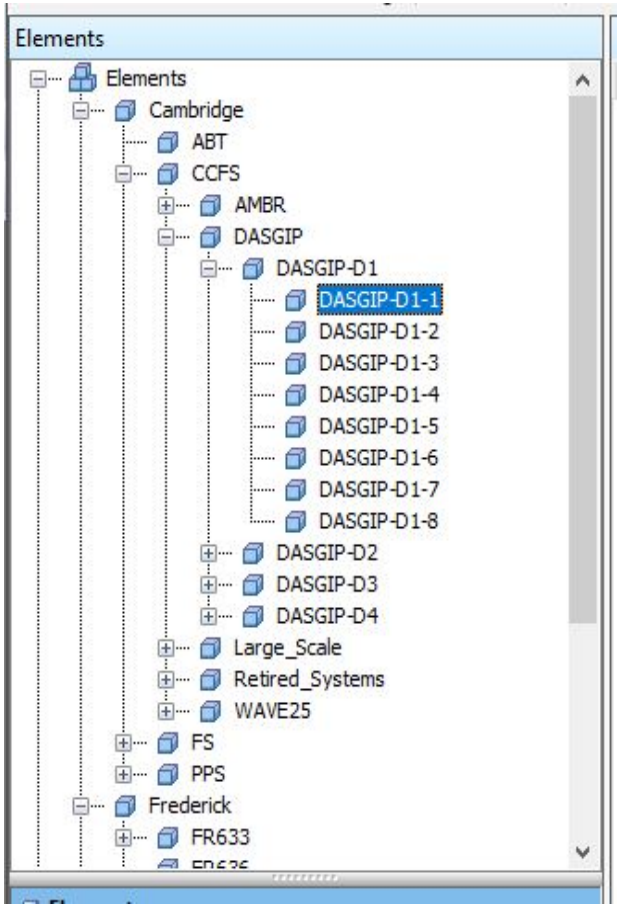
- Enterprise Data Migration
  - > 1 TByte of data to move
  - AF assets and tags
  - >>75,000 tags
- Site Data Migration
  - 93 Interface Nodes (Green) to repoint to servers in Bronze
  - 21% Interface Nodes are GMP
  - 28% labs are GMP

Challenge 4 – Providing Value for the Customer

- Asset management
- Improved user interface
- Improved speed and collaboration across sites
- Capability for Golden Batch

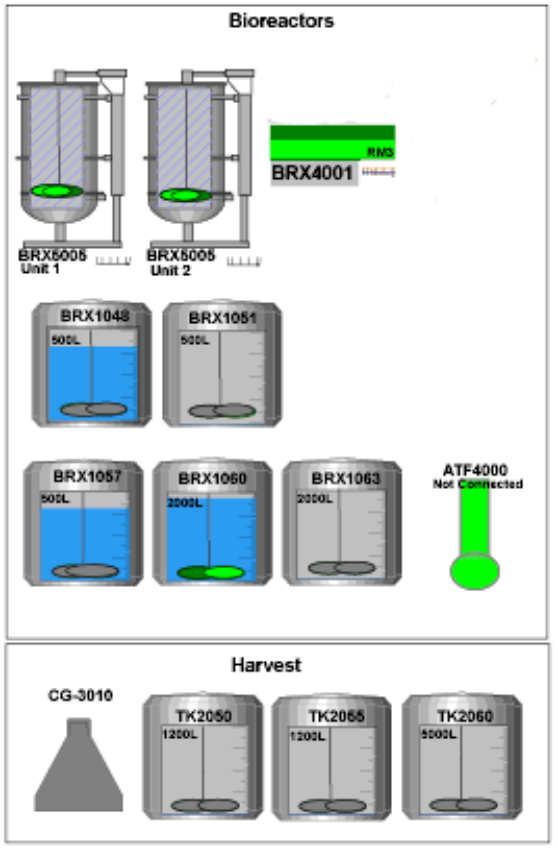
Customer Value – Tags & Assets

- Deployment of new assets with templates
- Standardized navigation for assets allowing users to quickly find instruments and data of interest
- Ability to integrate process data with other asset context
- Alignment with AZ standards for tag naming and architecture



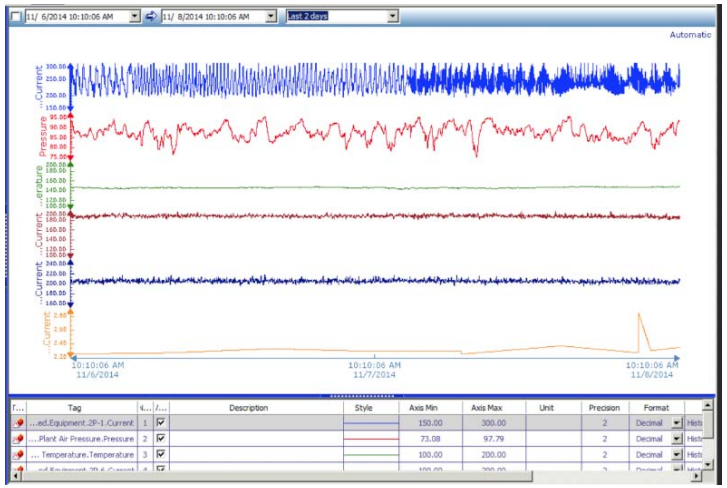
Customer Value – User Interface

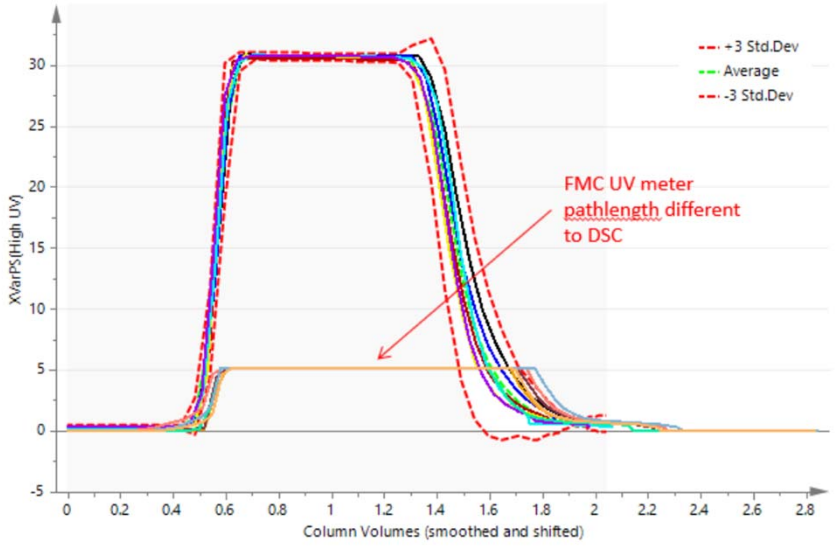
- An enhanced, web-based, user experience
- Increased application stability
- Ad hoc report creation without needing local PC installs, reducing overhead for our support teams and our users
- Improved reporting for GMP equipment
- No interruptions to critical processes in our R&D labs and for pilot plant operations

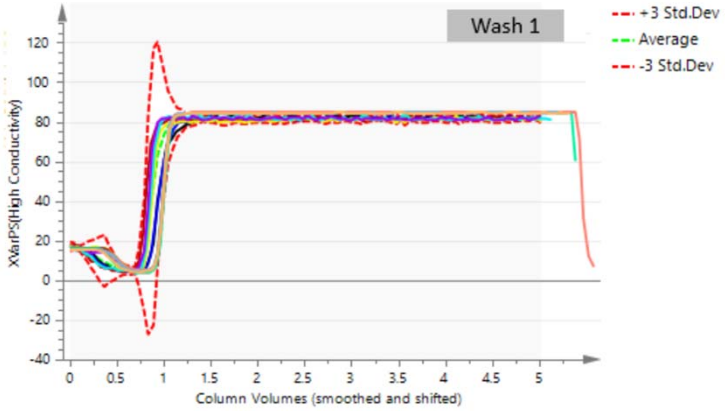


Customer Value – Future

- AWS cloud supports better collaboration across sites
- Capability to determine “Golden Batch”
- Ability to use mobile devices







In Summary

Challenge

- Build PI in a secure infrastructure in the cloud
- Validate the upgraded system in an agile way
- Migrate the data with no down time for the business
- Provide value for the customer

Solution

Built and qualify the latest OSI PI system in the AWS cloud using a secure infrastructure and the OSIsoft best practice for implementation

Benefits

- Improved security
- Improved user interface
- Easier collaboration across sites
- Improved asset management & visualization
- Application stability
- Capability for Golden Batch

Acknowledgements - Project Team

- IT
  - Project Manager – Jessica Lockard
  - Architect – Adolf Brown
  - System Engineer – Jeff Owen (Automated Results)
  - Business Analyst / Test Lead – Joe Hofmann
  - Business Relationship Manager – Ram Gupta
  - Vendor (OSIsoft)
- Business
  - Manufacturing Sciences – Mike Shackleford, David Krell
  - BPD Informatics – Ben Flores
- QA
  - Business – Joshua Levine
  - IT – Ramiro Ruiz Casillas

Glossary of Terms

- ALSS – Automation Lab Shared Services
- AWS – Amazon Web Services
- AZ – AstraZeneca
- BLA – Biologics License Application (milestone)
- CD – Drug Candidate (milestone)
- Dev – Development Environment
- FMC – Frederick Manufacturing Center
- GMP – Good Manufacturing Practices
- GPF – Gaithersburg Pilot plant Facility
- HA – High Availability
- IND – Investigational New Drug (milestone)
- IOQ – Installation Operational Qualification
- IQ – Installation Qualification
- LAN – Local Area Network
- PCN – Process Control Network
- Prod – Production Environment
- QA – Quality Assurance
- QC – Quality Control
- SOP – Standard Operating Procedure
- UAT – User Acceptance Testing


謝謝
DZIĘKUJĘ CI
TAPADH LEIBH
KEA LEBOHA
NGIYABONGA
БАЯРЛАЛАА
MISAOTRA ANAO
TEŞEKKÜR EDERIM
WHAKAWHETAI KOE
DANKIE
TERIMA KASIH
DANKON
TANK
TAPADH LEAT
СПАСИБО
GRAZIE
MATUR NUWUN
ХВАЛА ВАМ
MULȚUMESC
РАКМЕТ СІЗГЕ
고맙습니다
GRAZIE
شكرا
FAAFETAI
GO RAIBH MAITH AGAT
ESKERRIK ASKO
БЛАГОДАРЯ
GRACIAS
THANKYOU
HVALA
ТИ БЛАГОДАРАМ
TEŞEKKÜR EDERIM
DANK JE
ΕΥΧΑΡΙΣΤΩ
GRATIAS TIBI
OBRIGADO
TAK
DANKE
AČIŪ
SALAMAT
MAHALO IĀ ʻOE
TAKK SKAL DU HA
MERCI
RAHMAT
MERCI
GRAZZI
ÞAKKA ÞÉR
ありがとうございました
DI OU MÈSI
ĎAKUJEM
HATUR NUHUN
PAXMAT САГА
SIPAS JI WERE
TERIMA KASIH
CẢM ƠN BẠN
UA TSAUG RAU KOJ
WAZVIITA
ТИ БЛАГОДАРАМ
СИПОС
KÖSZÖNÖM
GRÀCIES
SALAMAT
MAHADSANID
FALEMINDERIT
HVALA
ДЗЯКУЙ