Bio-Analytical Technologies

Your Partner in Business
With
Solutions That Make A Difference

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Case Studies

How do we make a Difference?

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UV-VIS Instrument Software (USA)

- Objectives
  - Obsolete Processor Replacement
  - Software Enhancements to Support Additional Applications
  - Integrate Auto Sampler
- Challenges
  - Form Factor Constraints
  - Standards Compliance
  - Integration Framework Missing in Original Software
- Business Benefits
  - Product Life Extension
  - Minimal Change in Manufacturing Process
  - Increase in sales due to User Friendly Auto Sampler Integration
  - Lower Cost of Development

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Handheld NIR Instrument (USA)

- Objectives
  - Started with Porting of Linux Kernel on New Processor and Touch Screen
  - Extended to Full Product Software Testing
  - Extended to Development Ownership of Entire Firmware & Software
- Challenges
  - The Original Product Developers Had Left the Company after Acquisition
  - Coordination with In-House FPGA Development and Hardware Design Partner
  - Intellectual Property Related Concerns
- Business Benefits
  - Cost of Ownership of Product Reduced
  - Reduced Time to Market for Product Upgrades
  - Risk of Skills Attrition Mitigated

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Laboratory Instrument Transformation (India)

- Objectives
  - Transformation of Laboratory Instruments Due to Hardware Component Obsolescence
  - Enhancement of User Interface
  - Integration of Standards Compliance and Report Generation
- Challenges
  - Lack of Software Documentation for Core Algorithm
  - Limited bandwidth of Client R&D Team
  - Intellectual Property Related Concerns
- Business Benefits
  - Disruptive Innovation in Hardware-Software Approach
  - Lower Cost of Transformation Due to Common Platform Development
  - Effective Change Management Due to Phased Transformation
  - New Revenue Streams Due to Controlled Yet Easy Software Feature Availability
  - 21 CFR Part 11 Compliant
  - Improved Client Satisfaction

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Android Based Endoscope & Vital Signs Monitoring Handheld Device

- Objectives
  - Lower The Cost Of Vital Sign Monitoring & Endoscopy For Simple Procedures
  - Make Them Easy To Use For Homecare & Small Clinics
  - Telemedicine Capability
- Challenges
  - Ability To Support Any SPO2 Sensor & Endoscope With USB Connectivity
  - Technical – Protect USB Port On Tablet From Power Surge, Out Of Box Video Support For USB Camera Not Available In Android
  - Must be Usable by Least Trained Medical Nurse
- Business Benefits
  - Android App Provided Powerful Yet Cost-effective Solution
  - Multiple Business Model Variations – Offline Local Storage, Cloud Storage/Backup, Multi User Mode
  - Remote Patient Health Assessment in Real Time
  - Unreachable Market Segments Opened Up

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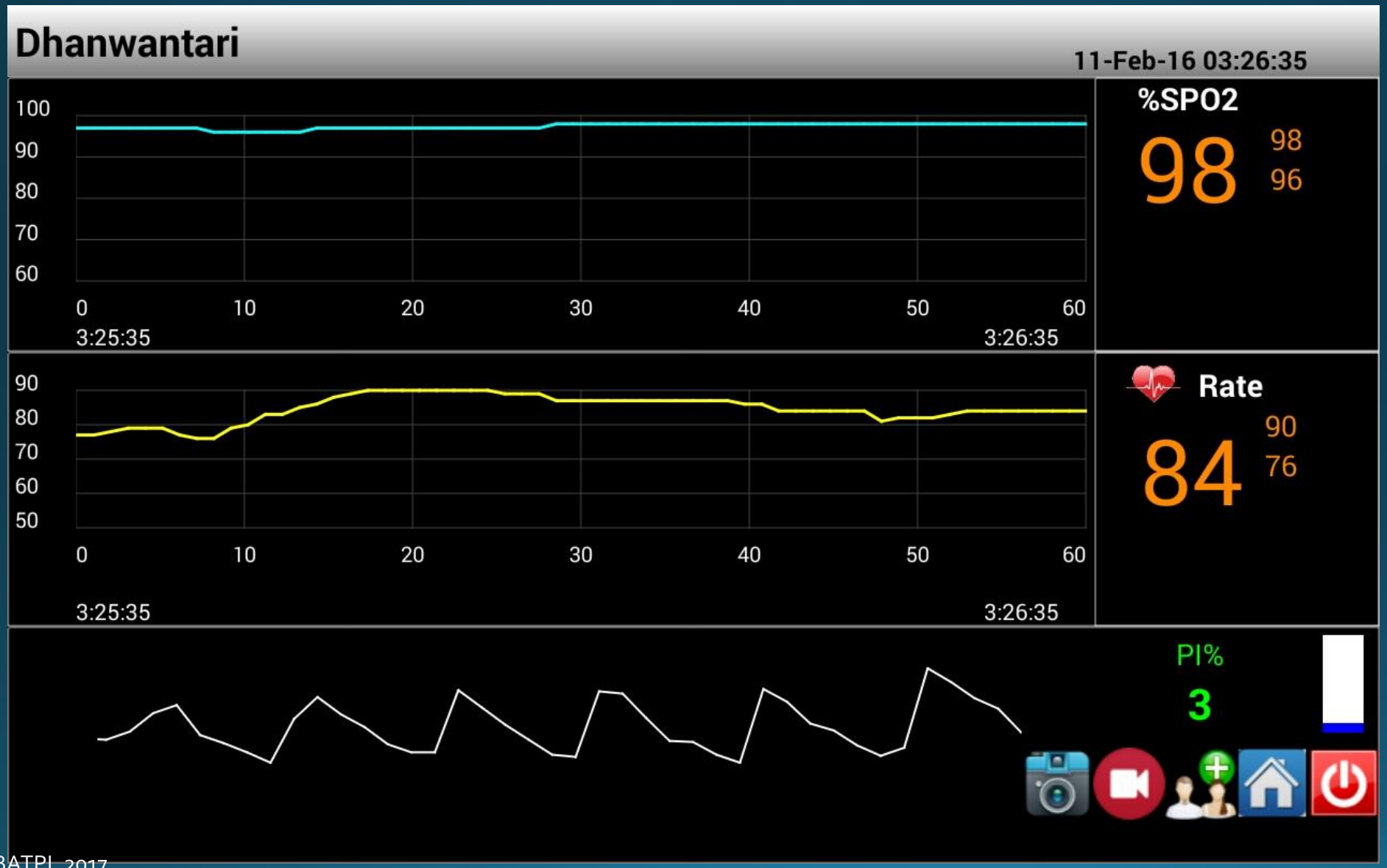

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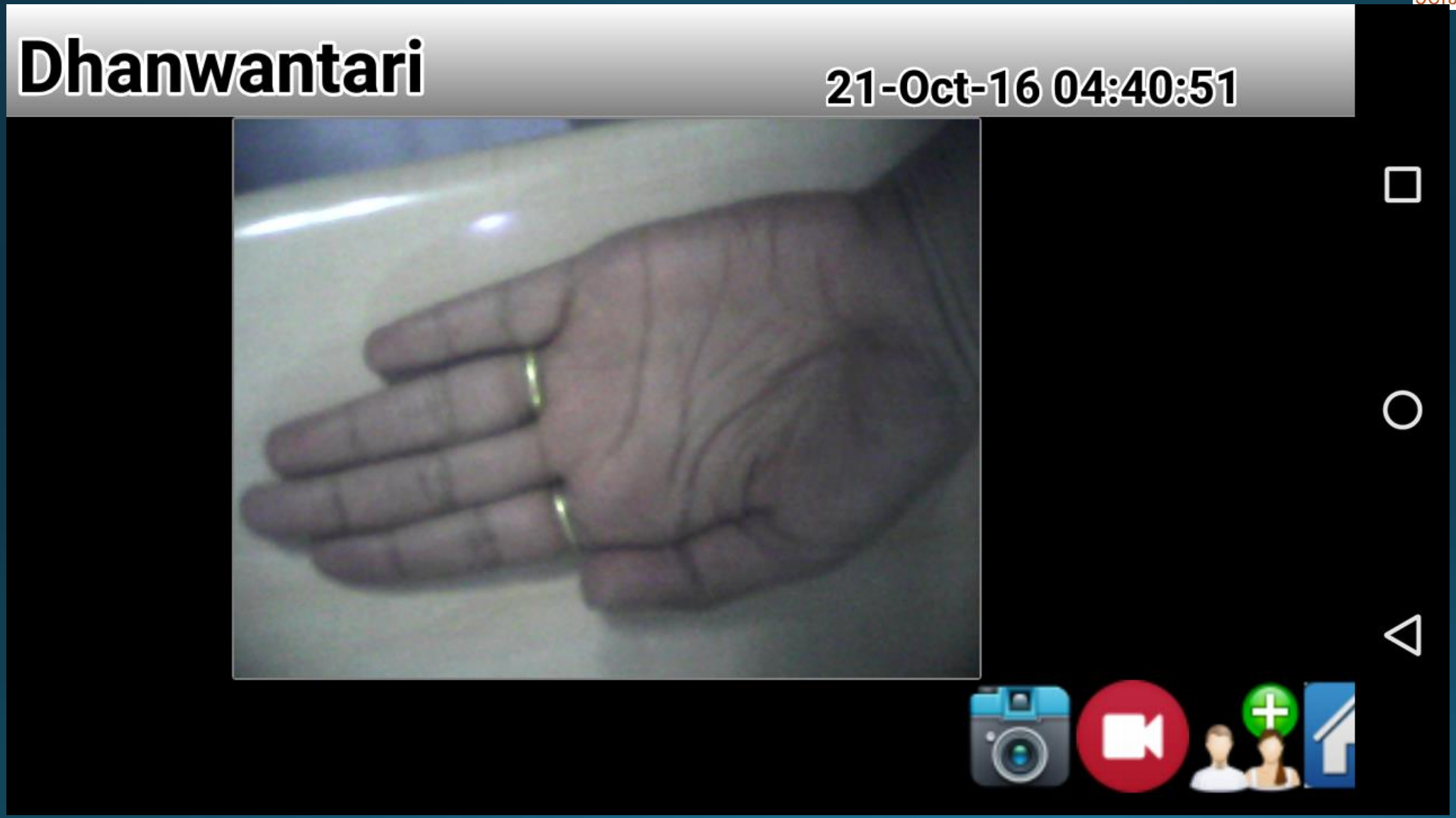

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Wearable Ambulatory BP Device Software Upgrade (USA)

- Objectives
  - Migrate Legacy PC Based Software Platform To Contemporary Technologies
  - Add Functionality To Match New Features Of Wearable Unit
  - Add Functionality To Match User Demands Like Internationalization, Client-server
- Challenges
  - Lack Of Documentation
  - Standards Compliance & Adapting Processes For Medical Software Development
  - Ongoing Hardware /Firmware Changes At Client R&D Center
- Business Benefits
  - Lower Cost Of Development
  - Full Support For Regulatory (IEC 62304) Compliance Processes And Documentation
  - Niche Skills Availability Without Long Term Liability

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LIMS Product Development (USA)

- Objectives
  - Architectural Changes and Maintenance of Highly Configurable Laboratory Information Management System (LIMS) for Wide Range of Process Industries with Advanced Sample Management, Scheduling and Instrument Integration Features.
- Challenges
  - Providing Workflow Configuration for Various Types of Laboratories
  - Generic Instrument interfacing capabilities
- Business Benefits
  - Cost per Feature and Cost of Ownership Reduced
  - Increased Profitability
  - Improved Response to Custom Enhancements and Systems Integration
  - Retention of Customers in Competitive Market

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Critical Enhancement for Analytical Instrument Software (Japan)

- Objectives
  - To improve instrument sales with addition of Template Based Printing Feature
- Challenges
  - Prioritization of Requirements not clear/hard to achieve
  - Customer's first experience of outsourcing from company HQ
  - Intellectual Property Related Concerns
  - Customer's processes not geared towards outsourcing
  - Language and Culture barriers
- Business Benefits
  - Very Distinctive Feature with Superb Usability Boosting Instrument Sales
  - Successful Demonstration of Outsourcing
  - Foundation for Informatics Software
  - Paved the way for many other existing software to be integrated in Phase 2

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MALDI Imaging (UK)

- Objectives
  - Develop Image Control & Image Gallery
  - Enable Above To Consume Processed Data From Raw MS Data
  - Add Data Analytics Capability Including Mathematical And Statistical Algorithms
  - Add Support For Various Ion Sources To Configure Ion Source Through MS Control S/W
  - Use Histopathology Images To Setup Experiments
- Challenges
  - Zero Learning Curve For Users To Migrate To New Product
  - Component Centric Software Development In Different Time zones
  - Availability Of Subject Matter Expert Had To Be Augmented By Self-study
- Business Benefits
  - Single Product Providing Integrated Workflow That Improved User Experience As Against Working With Multiple Applications
  - Client Concentrated On Core Capabilities Supported By Bat's Imaging Skills
  - Lower Cost Of Development & Testing
  - Reduce Time To Market

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Rating For Steel Inclusions Using Imaging (UK)

- Objectives
  - Migration Of Legacy Software From An Older Technology & Design To Newer Technology And Design
  - Add / Update Algorithms To Feature Detection
  - Integrate Hardware Interfaces And Third Party Imaging Tools
  - Updating The Framework To Include Image Documentation Tools (Annotation & Measurements)
- Challenges
  - Developing Feature Detection Algorithms Without Customer Support
  - Developing The Application In Simultaneously With Development Of The Base Framework
  - Low Availability Of Subject Matter Expert
  - Low Documentation On Legacy Software And Code
- Business Benefits
  - Justified The Investment On The Framework
  - Acted As A Proof-of-concept For Future Applications To Be Developed On The Framework
  - Intuitive User Interface With Enhanced Functionality
  - Reduced Time To Market

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Integrating Third Party HPLC to MS Software (Canada)

- Objectives
  - Device Driver for HPLC Stack
- Challenges
  - Single Line Requirement As Above
  - Working With Two Organizations to Obtain Information
- Business Benefits
  - Reduced Development Cost
  - Enhanced Possibility of Sales Due to Integration

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TOF Instrument Development, Testing, Extended Application (UK)

- Objectives
  - Include TOF Support in MS Software
  - Medical Diagnostics Imaging Software Using MALDI Source
- Challenges
  - Mapping TOF Workflow Requirements to Existing Software
  - Setting Up TOF in India Labs
  - Defining Requirements for Imaging Software
- Business Benefits
  - TOF – Virtually 24/7 Development Time – Reduction in Schedule
  - Mimicking End User Testing
  - Helping Company Venture Into Developing Medical Diagnostics Software

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Analytical Services For Research, Development & Bio-analysis

- Objectives
  - Develop Sensitive & Selective method for Tenofovir (Anti-HIV) from Human Plasma
  - Validate as per US FDA Guidelines for Bioanalytical Method Validation
  - Execute the sample analysis as per the US FDA guidelines
- Challenges
  - Method is developed for the Analysis of Active drug and not pro-drug
  - Matrix quality is not consistent as samples are collected from different parts of India
  - Refinement of method for drug sensitivity
  - LOD (Limit of Detection) ~ 1 ng/mL & LOQ (Limit of Quantitation) ~ 5 ng/mL
  - 3 fold linearity – 1 ng/mL to 1200 ng/mL
- Business Benefits
  - Improved Monitoring of Patient Drug Regiment Adherence
  - Low Sample Processing Cost
  - Lower cost of method development & validation
  - High quality data passes scrutiny by auditing & funding authorities

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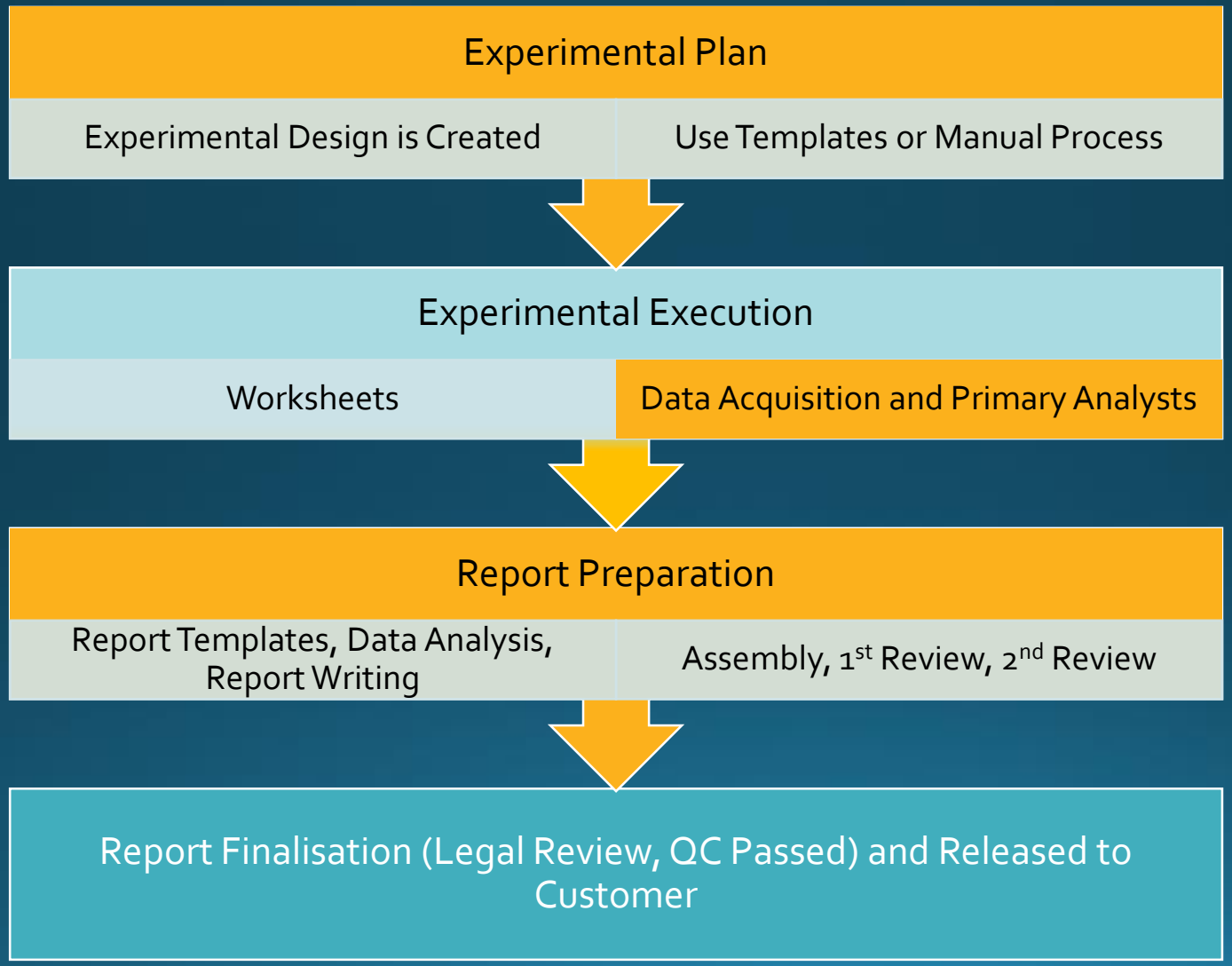
Human Identification Workflow Automation as Kit Companion



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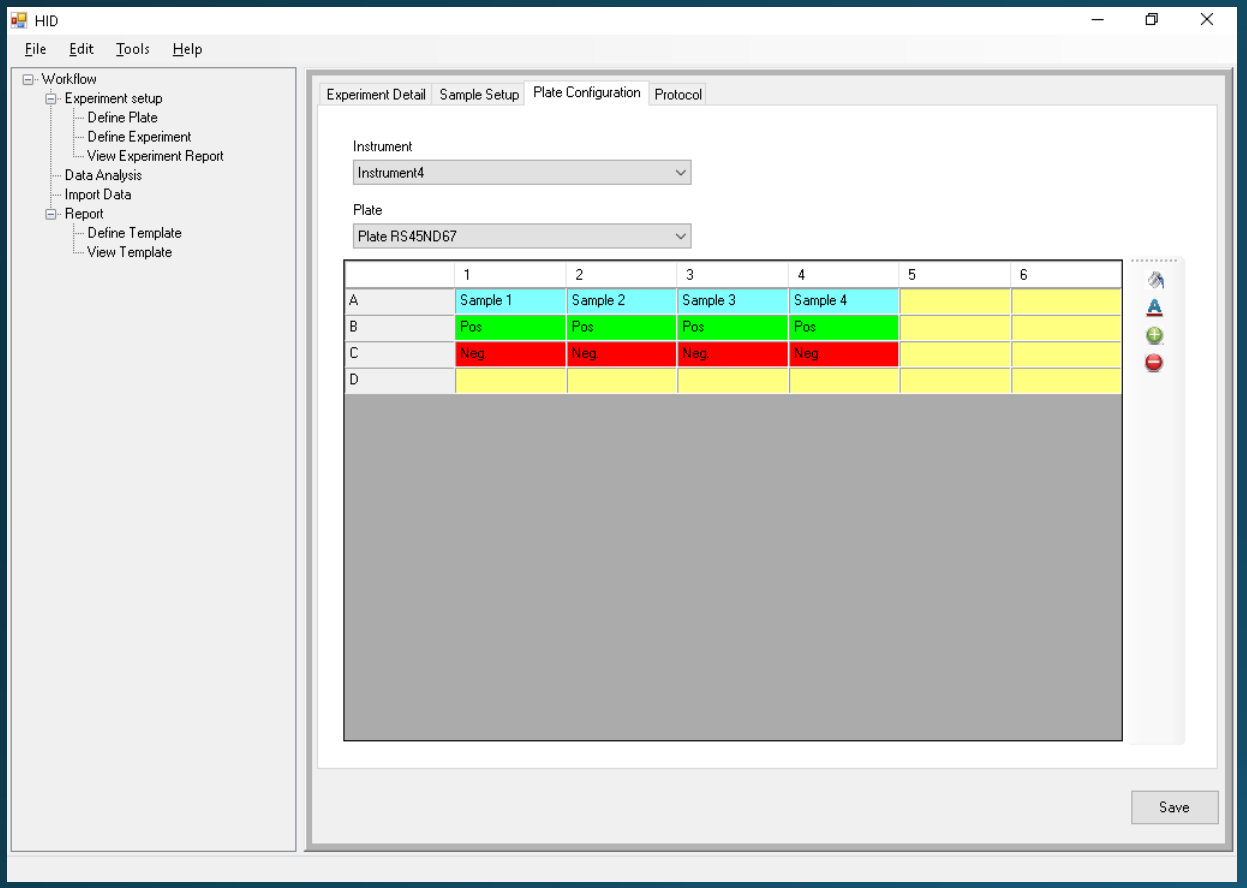

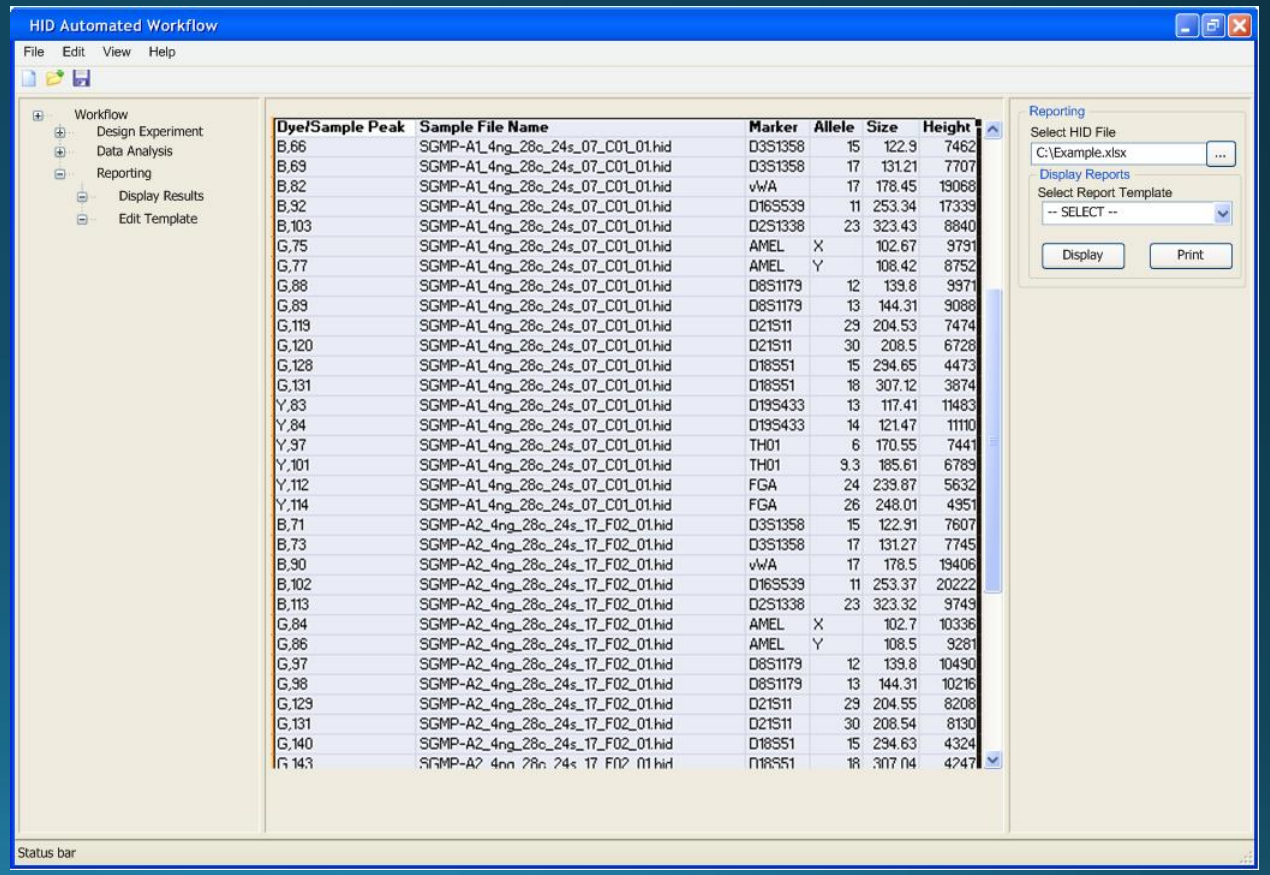

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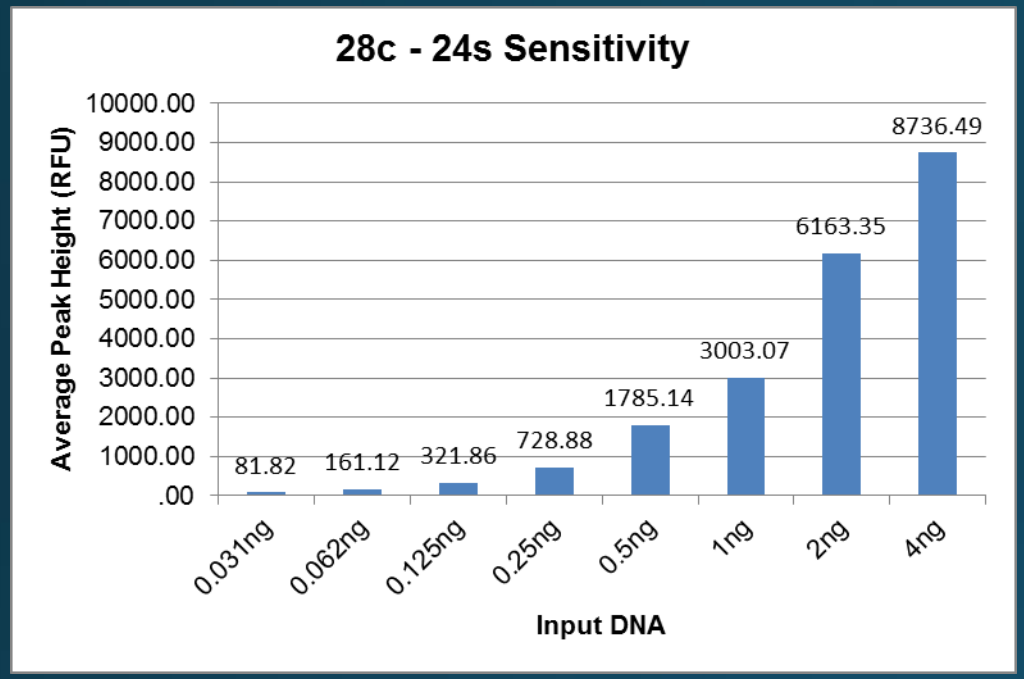

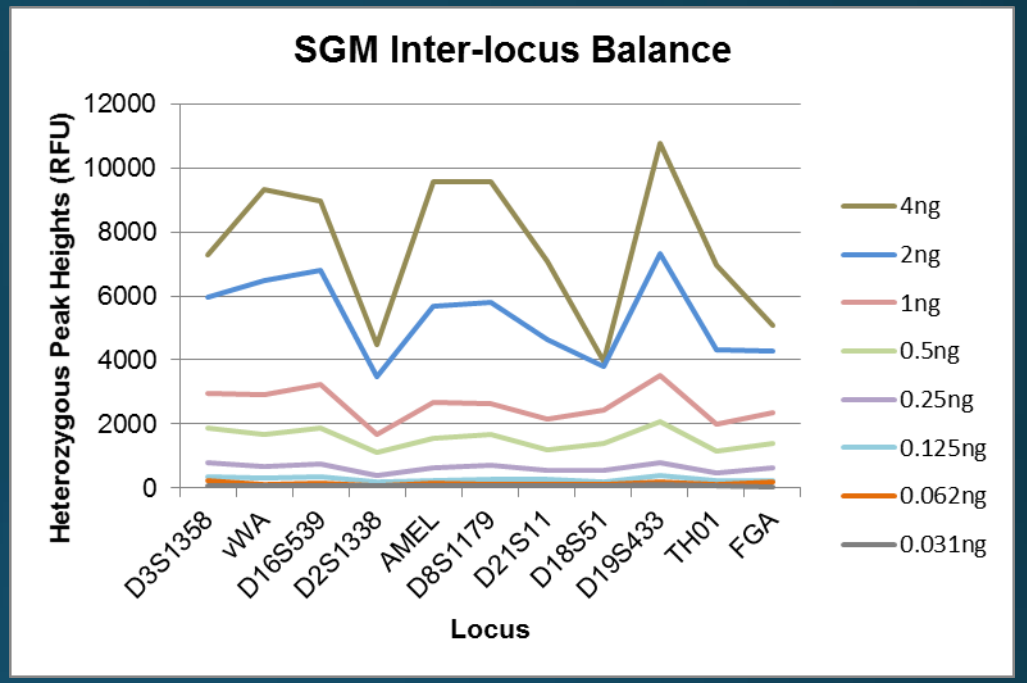

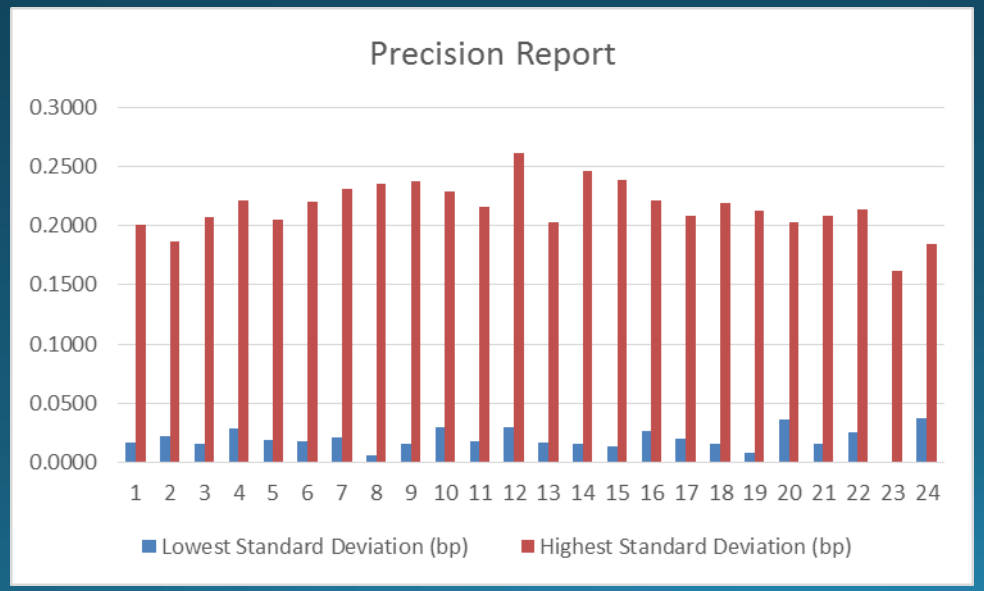

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BioClinical - Software Product Clinical Trial Management (India)

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- Objectives
  - Generic Drugs BA/BE Studies Management with 21 CFR Part 11 Compliance
- Challenges
  - Varied nature of client requirements
  - Long Validation Cycle & Extensive Support to Customer During That Period
- Business Benefits
  - Holistic 21 CFR Compliance Improving Chances of Trial Success
  - One Year ROI Due to Reduction in Cost – Paper, Document Storage, Shorter Review Cycles, Optimize Staff and Volunteer Deployment
  - Reduction in Trial Failures Risks –Automation & Control Points in Volunteer, Sample, Pharmacy Management
  - Improved Client Satisfaction Due to Transparency & Reliable Reporting

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Pollution Monitoring Data Collector

- Objectives
  - Gather Data From Pollution Monitoring Instruments
  - Send Data To Central Pollution Control Board Over Internet
- Challenges
  - Wireless Network Reach Required for Instruments Spread of Large Area Horizontally & Vertically
  - No Onsite User Interaction Allowed for Data Integrity
  - Fail Safe Operation With Loss Less Data
- Business Benefits
  - Increase Market Share
  - Modular Product Offering

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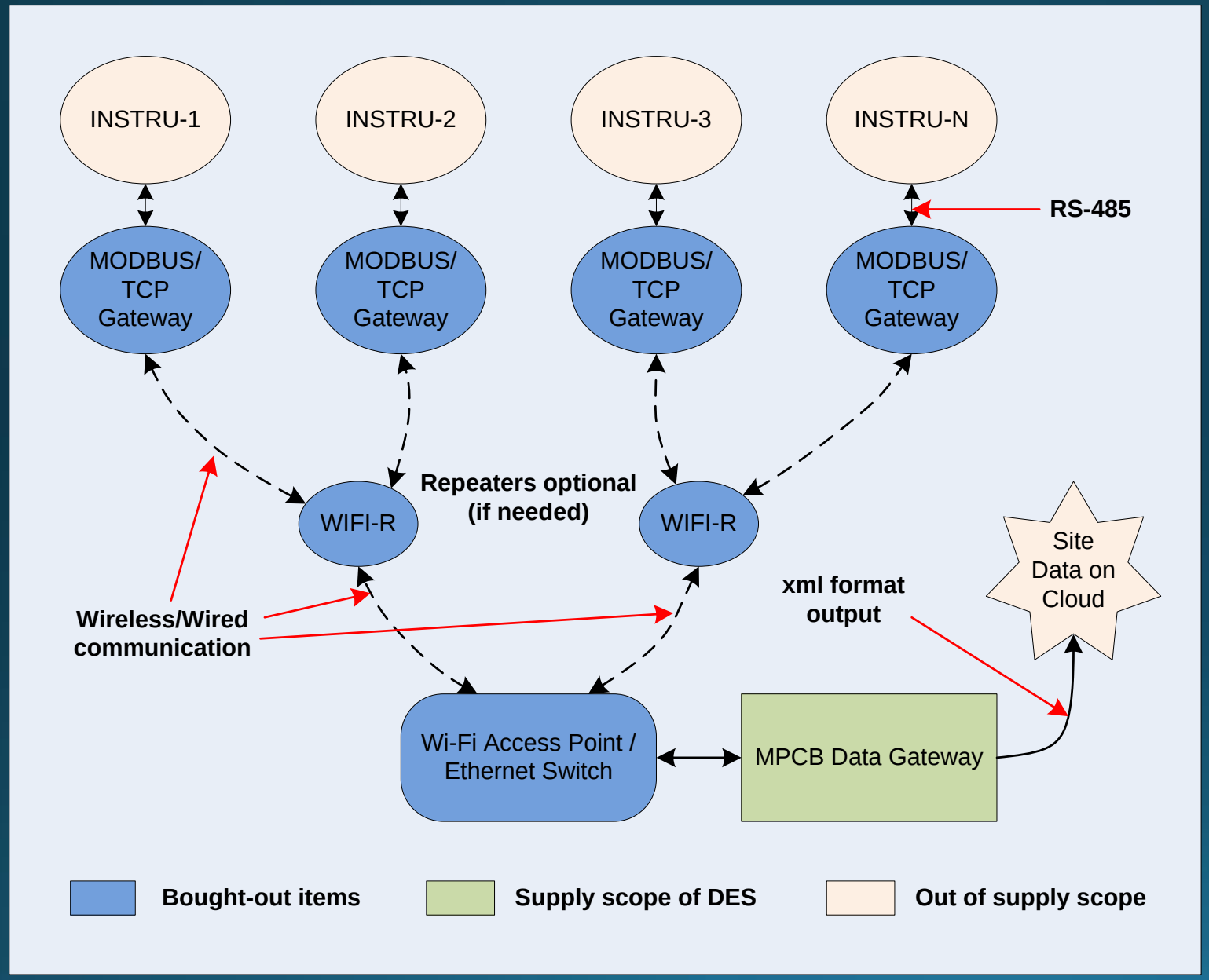
INSTRU-1
INSTRU-2
INSTRU-3
INSTRU-N
RS-485
MODBUS/ TCP Gateway
MODBUS/ TCP Gateway
MODBUS/ TCP Gateway
MODBUS/ TCP Gateway
WIFI-R
Repeaters optional (if needed)
WIFI-R
Site Data on Cloud
xml format output
Wireless/Wired communication
Wi-Fi Access Point / Ethernet Switch
MPCB Data Gateway
Bought-out items
Supply scope of DES
Out of supply scope

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Dedicated Relationship Center Air-Conditioning Electronics (India)

- Objectives
  - Establish Non-Core Embedded Design-Development Competency For Entire Product Lifecycle (Design to Field Support)
- Challenges
  - Coordination With Japanese Domain Consultant and Local R&D Team
  - Standardization of Components for All Product Lines
  - Establishment of Third Party Manufacturing
- Business Benefits
  - Total Control Over Critical Components of System Removing Risks of Dependence on Overseas Black Box Suppliers
  - Reduced Time to Market for Variants
  - Superior Field Deployment and Diagnostics
  - Agile Team Sizing Reducing Cost of Ownership

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Universal Power Convertor Controller

- Objectives
  - Configurable Power Outputs (Frequency & Amplitude)
  - Preferential Input Power Source(s) Configuration
  - Variety of Display & Communication Protocol Support
- Challenges
  - Tuning For Variation Of Power Components Like Transformers, Chokes & Power Devices
  - Cost And Size Optimization With Respect To Existing Market Products
  - Congregation Of Multiple Business Logic With Configuration Control
  - 24/7 Instrument Operation Reliability
- Business Benefits
  - Simplification of Production Process
  - Reduction in Product Lifecycle Costs
  - Improved Servicability
  - Scalability For Extended Features`

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Automobiles On Board Diagnostic Device Manager

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- Objectives
  - ISO 15765-4 Compliant OBD Device In A Vehicle
  - Wireless Interface With Android Devices And Remote Web Server Application
  - Local Geo-position Information For Geo-fencing
  - Compact Device Size And Cost Optimization
- Challenges
  - Component Selection To Cover All Features With Cost And Size Optimization
  - Auto Detection Of ISO 15765-4 Variations
  - Integration Of BGA Packaged BT Modules
  - Limited Availability Of Client's R & D Team
- Business Benefits
  - Low Cost, Small Size
  - Wireless Connectivity With Off The Shelf Android Devices
  - Local Information Display About Vehicle Health For Vehicle Driver
  - Remote Information About Vehicle Health And Location For Vehicle Owner

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Phaco-emulsifier System Controller

- Objectives
  - Develop Cataract Surgery Instrument Indigenously Within Certain Cost Point
  - Instrument Must Have Differentiators To Reduce Entry Barriers
- Challenges
  - Client Having Trading Business Model Venturing In Design, Development, Manufacturing
  - Dependency Management - Client Responsible For Development Of Mechanical Parts Whereas BAT Responsible For Electronics & Firmware
  - Vacuum Sensing With Required Accuracy And Fast Control Response
  - Controlled Ultrasonic Drive For Probe
  - Macroscopic Flow Control
- Business Benefits
  - Leveraging BAT Experience To Complement Client's Market Experience To Define Product Differentiators
  - Extensive Support For Patient Safety & Regulatory Compliance (IEC 62304)

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High Definition Medical Video Recording, Distribution & Management System

- Objectives
  - To Record And Display High Definition (1080p, 60fps) Video Signal With Minimum Latency
  - Multi Media Signal Streaming Over Ethernet Network
  - GUI Interface To Read, Write, Record, Configure Video Signal & Parameters
- Challenges
  - Zero (One Frame) Latency For Display And Streaming
  - Recording Video At Multiple (Three) Storage Devices
  - Cost Optimization
- Business Benefits
  - Low Cost Import Substitute
  - Modular Structure For Ease Of Production
  - Serviceable Indigenous Product

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Solar (PV) Power Plant Data Acquisition, Panel Tracking & Control System

- Objectives
  - Design Integrated PV Panel Tracking Control & Power Parameter Data Acquisition System
  - Wireless Network of Panels
  - Remote Monitoring
- Challenges
  - Ad-hoc Wifi Network Organization Protocol
  - Implementation Of Solar Tracking Algorithm
  - Impediment, Rain, Wind Speed, Power Parameter Sensing With Suitable Control Action
- Business Benefits
  - Modular System Scalable To Any Size
  - Cost Optimization
  - IoT Based Remote Monitoring

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Customer is Always Right!

Testimonials

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Brooks Life Science Systems

- The BAT team are very professional, we have good communication and engagement with the team who are able to demonstrate a strong mix of life science application and software technical knowledge. This balance has delivered value in practice, allowing teams to get up to speed with our projects efficiently, and deliver on commitments without the need for constant supervision.

- Gary Coulthurst,
  Software Quality Assurance

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PerkinElmer

- Our company has partnered with BAT on multiple projects encompassing instrument control software which has yielded technology and time-to-market benefits to PerkinElmer. The BAT team is extremely capable, dedicated, has excellent domain knowledge and software development expertise. When needed to meet product deadlines the BAT practitioners have gone the extra mile and the BAT management has always lived by their vision statement of "Solutions that make a difference.

- James Custus,
  Chromatography Software Manager

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Shimadzu Analytical Instruments

- Shimadzu engaged Bio-Analytical Technologies (BAT) for an important addition across its software products suite. BAT designed and developed the application where we found that they are reliable service provider who treated Shimadzu as a valued customer. BAT delivered the solution with utmost flexibility yet as planned, on schedule which really made a difference to Shimadzu. At Shimadzu we definitely would consider BAT as a long term partner.

- Ryuji Nishimoto,
  General Manager
  Research & Development Department
  Analytical & Measuring Instruments Division

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Thermo Fisher Scientific

- We at Thermo-Fisher Scientific find BAT a reliable and capable partner. They have demonstrated a singular focus towards meeting our expectations. It demonstrates the effectiveness of mature processes followed by both the organizations backed by capable staff and leadership.

- Global Test Manager, Chromatography Software

Chromatography and Mass Spectrometry

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Waters

- The partnership with BAT has been a contributing factor in achieving the business goals for Waters MS division. We are pleased with the commitment and dedication exhibited by BAT practitioners and management. BAT has a team with strong domain and software life cycle expertise. BAT can be proud of its vision statement of solutions that make a difference

- Richard Chapman

Director ICS MS, Principal Research Scientist

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Capabilities

Who Are We?

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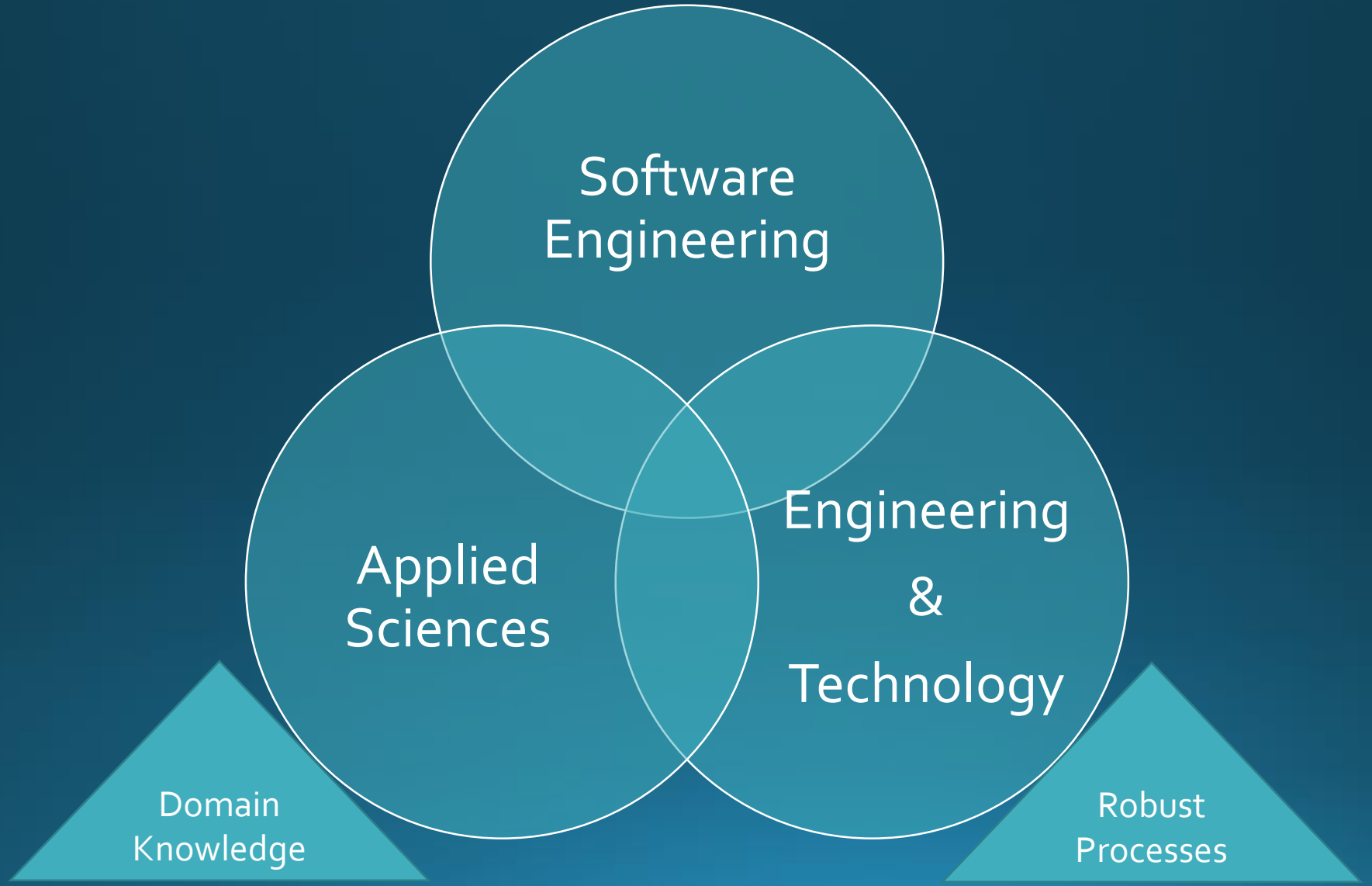
Value Foundation: IP Enhancement



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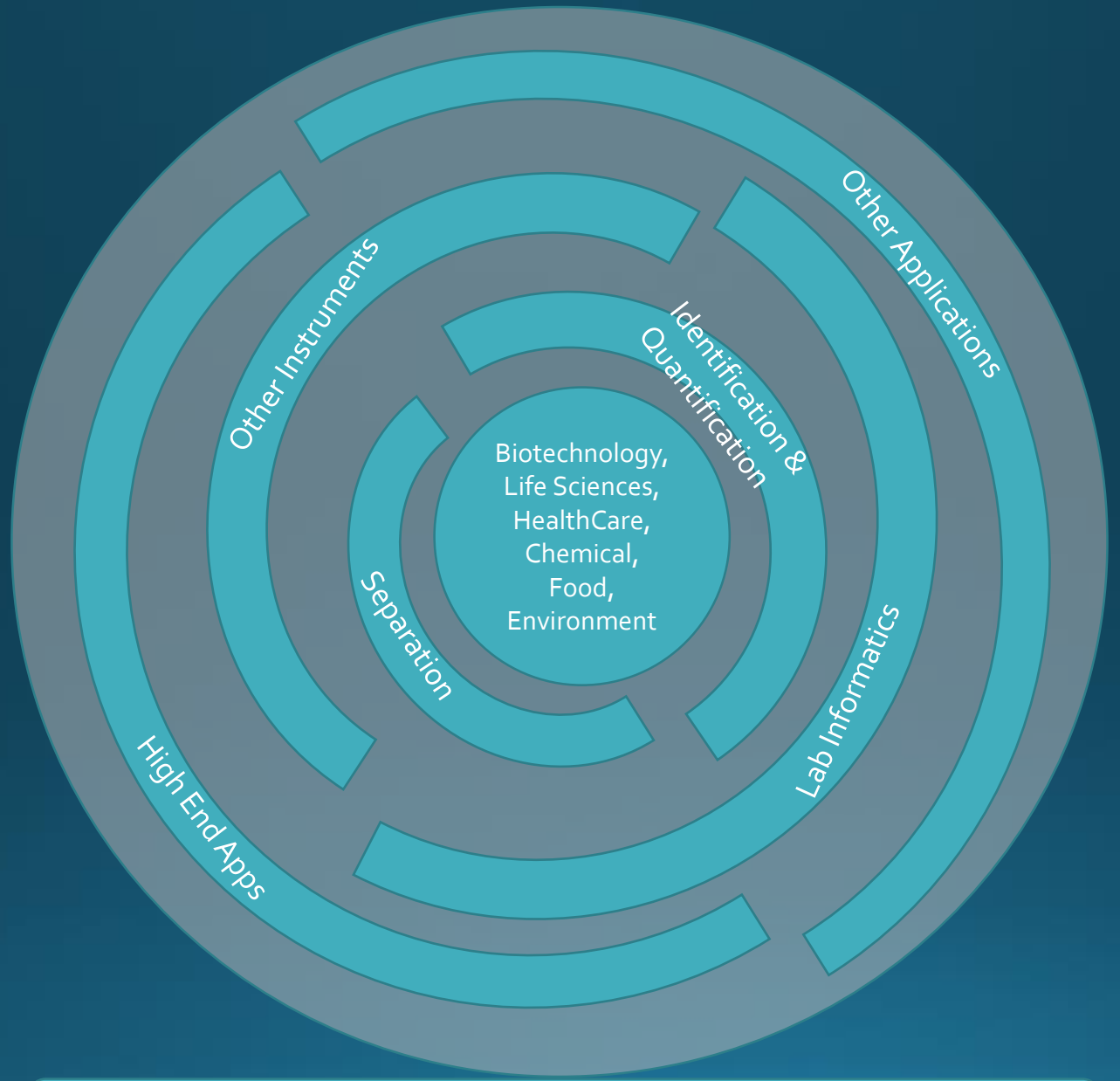
- End User Applications
- Application Integration
- Lab Informatics
- Instrument Integration
- Control-Monitor
- Firmware
- Hardware

- Compliance
- Interpretation
- Analysis
- Data Collection
- Method Design



One Decade Of Experience in Serving Clients Globally

- Servicing
- Installation | Integration
- Software Maintenance
- User Testing
- Software Testing
- Development-Transformation
- Design
- New | Legacy

- Big Data Analytics
- Mobility
- Internet Technologies
- Java & Open Source
- RTOS, Linux, Microsoft
- Microprocessors

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21 CFR Part 11

- Implementation As Part of New Software – CDS, LIMS, CTMS
- Gap Analysis
- Modification For Compliance
- BAT Framework for Microsoft and Java Platforms To Make Legacy Software Compliant in Short Period of Time
  - Authentication & Authorization
    - Framework Provided or Host Application Provided
  - User Interface
    - Look & Feel Harmonization
  - Internationalization
  - Reporting
- Computer Systems Validation & SOP Validation

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Bio-Analytical Domain

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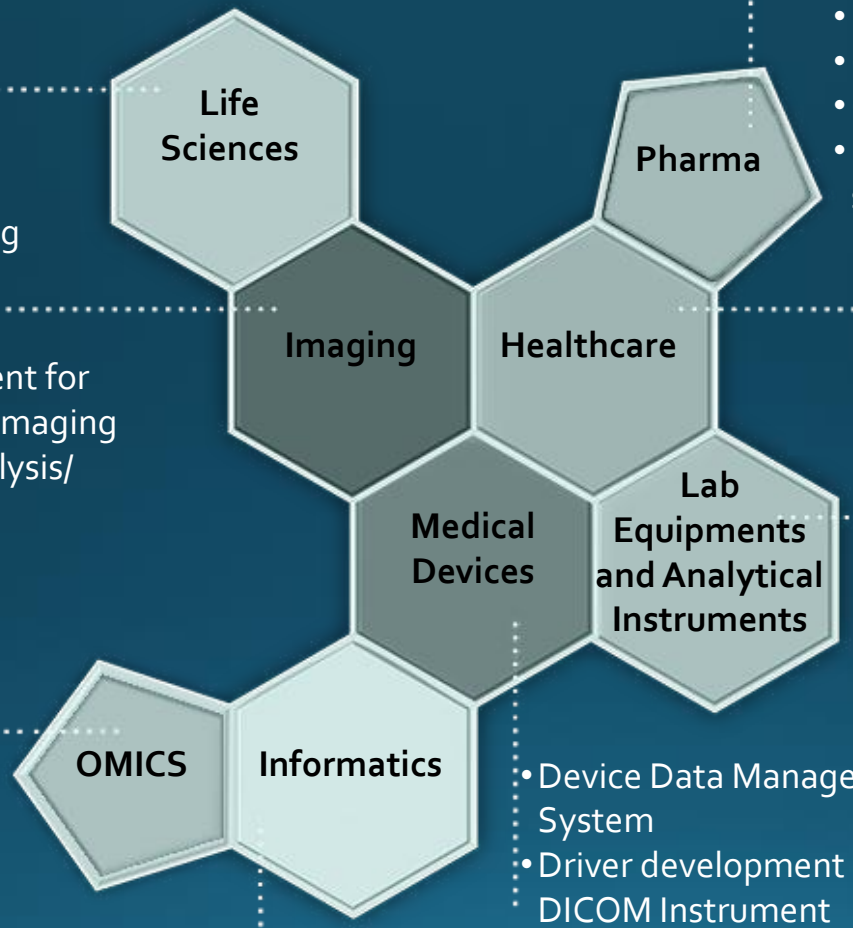
- Method Development
- Productization of research
- Workflow automation for R&D labs
- Bio-Banking System Development
- Data acquisition, analysis, graphing and reporting
- System Integration



- Pre-clinical Sample Testing
- Clinical Trial Management System
- Computer System Validation Services
- Method Development and Validation
- Gap Analysis for compliance 21CFR Part11
- GxP
- Feature development to meet compliance standard

- Application development for Biomedical, Industrial Imaging
- Image Processing/ Analysis/ Visualization
- Standards- MALDI

- Custom Web-based/ Desktop Application
- Product Development
- EMR/EHR Development
- Healthcare Information Management and Data Analysis system
- Clinical Laboratory Software

- Genome Annotation
- Statistical Analysis of the Genomic Data
- Differential Gene Expression Analysis
- Gene Set Enrichment Analysis
- Pathway mapping
- Interpretome analysis

- Custom Application development
- Storage Management Solutions
- Instrument Interfacing
- Services for HPLC, LC–PDA and LC- MS/ MS, UV-Vis Spectroscopy
- Data Analysis System
- Device Drivers Development
- Method Development & Validation
- Black Box Testing
- Internet of Things
- New Instrument Development
- Obsolescence Sustenance

- LIMS/ ELN Development & Implementation
- Extension Development
- GxP, 21CFR Part 11
- Testing

- Device Data Management System
- Driver development and DICOM Instrument interfacing
- Hardware component design
- IEC 62304 Compliance
- Obsolescence Sustenance

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Why Work With BAT?

- We Have Domain Expertise Therefore We Understand Your Requirements Quite Well With Minimum Involvement From Your Team!
- We Have Worked With Many Clients Across The Globe & We Can Share Best Practices Without Violating Their Confidentiality But Improving Your Solution!
- We Can Provide End to End (Chip to Cloud) Services for Your Products!
- We Maintain Focus on Your Business Objectives Behind The Work That You Have Entrusted Us to Do!

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Software Services

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New Development	Sustenance	Value Added	Testing	Domain
• Application Design & Development • Product Engineering • Software Integration	• Maintenance • Modernization • Instrument Integration • Product Extensions • Product Professional Services	• Architectural Consultancy • 21CFR Part 11 & GxP Compliance Enhancements • Usability	• Automation • Black Box • White Box	• Validation • Method Development • Secondary & Tertiary Analysis of NGS Data

Microsoft, Linux, Android, iOS

Java, C/C++, C#, Internet Technologies, Data Analytics

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Embedded Technology Services

Product Engineering	Sustenance	Value Added	Testing
• Product Conceptualization • Architecture and Design • Prototyping • Remote Monitoring • Internet of Things	• Maintenance • Modernization • Component Obsolescence & Upgrades • Kernel Upgrades	• Design Consulting • Optimization & FMEA analysis • Vendor Assessment • Vendor QA • Field Failure Diagnostics	• Testing Jigs Development • PCB Evaluation • Standards Testing • ROHS Compliance

8+ Bit Micro/Pico processors, controllers, Tool Chains, RTOS

Industrial Sensors, Various Bus Architectures, FPGA

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Engagement Models

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Time & Material

- Low Maturity of Outsourcing Processes
- Fluid Scope
- Customer Managed Projects & Risks
- Higher Costs

Managed Projects

- Matured Outsourcing Process
- Well Defined Scope of Work
- BAT Managed Project & Risks
- Optimum Costs

Dedicated Relationship Center

- Matured Outsourcing Process
- Application/Portfolio Lifecycle Management
- Experience with BAT
- BAT Managed Projects & Risks
- Best Value for Money

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Quick Statistics

- Established in 2003
- Headquarter at Pune, India 175 KM from Mumbai Airport
- Wholly Owned Subsidiary in London, UK
- World Class IT Infrastructure in 7 Storied Building
- ISO 9001-2015 Certified
- Executive Management Experience in Global Outsourcing Companies Like IBM
- 100+ Practitioners Including Domain Experts Experienced in Research & Laboratories

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World Class Infrastructure

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Data Center

Software Development Center

Wet Chemistry Lab

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Analytical Instrument Lab

Embedded Technology Lab

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ISO 9001-2015

Processes

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Principles For Robust Processes

- Processes For Architecture, Design & Delivery Management
- Controls & Processes Required For Objective Aligned Behaviour
- Cost-Schedule-Quality : Trinity of Constraints
- Risks Could Be Opportunities
- Manage Risks Proactively
- Exception Management Provides Business Value; NOT Routine Operations
- Changes Are Inevitable
- Communicate Appropriately & Adequately
- Intellectual Property Protection
- Support IEC 62304

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Key Aspects of Processes

- We Follow Agile Method
  - Frequent Verification & Feedback (Part of Risk Management)
- Method Adoption During Engagement Initiation
- Project Governance
  - Stakeholder Identification
  - Communication Contents, Methods & Periodicity
  - Change Request Control
  - Governance Board
- Risk Management
  - On-Site Presence/Visits or Off-shore Visits
  - Risk Plan
- Project Closure With Handing Over Assets to Customer
- HR for Capability Development
- ITS for Delivery Infrastructure

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Solutions That Make a Difference

Intellectual Property Protection

- Technical Security & Access Control
  - Virtual LANs, Version Control, Replication
- Physical Security
  - Dedicated Area
  - Access Controlled & Monitored If Required
- Legal Remedies
  - NDA
  - Cyber Laws

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Thank You!

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