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Documentum User Conference

Implementing GxPharma in Spain: Benefits & Lessons learned

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Implementing GxPharma in Spain

- Contents:
  - Introducing the actors
  - What has been done?
  - Benefits
  - Lessons learned
  - Still in route

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Introducing the actors

- Contents:
  - Introducing the actors
  - What has been done?
  - B&LL
    - Benefits
    - Lessons Learned
  - Still in route

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Introducing actors: the names

- **Probitas Pharma** is a multinational group, head of Grifols Group. Probitas Pharma activities cover R&D, manufacturing and sales while primarily focusing on blood derivates, reagents, diagnostic equipment and fluid-therapy products. Products are distributed both in Europe, South America, USA and Asia, in up to more than 70 countries. Probitas Pharma is one of the 5 main blood-derivates in the World with a great reputation of quality and security in their products.
- **Documentum**, is the leading Document Management solution provider in the LifeSciences/Pharmaceutical industry with a special focus on Compliance while providing solutions that “ease the way” in the Pharma value chain.
- **IBM Business Consulting Services** is the biggest consulting group with wide experience implementing Document Management Solution around the World, with great experience helping companies to achieve compliant DMS which has been successfully leveraged within GxPharma.

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Introducing actors: the actions

- Probitas Pharma has provided all the facilities to the IBM team to successfully implement GxPharma in Spain
- Documentum has provided the solution, GxPharma, fruit of the joint experience in Document Management by Documentum and IBM
- IBM Business Consulting Services delivered the solution by providing the team and management

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What has been done?

- Contents:
  - Introducing the actors
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  - Benefits
  - Lessons learned
  - Still in route

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What has been done?

- Probitas Pharma requested IBM BCS services for the implementation of a Document Management System under regulatory boundaries
- IBM BCS delivered their proposal based on the following:
  - Quick implementation
  - Roll-out approach
  - Configuration vs Development
  - Requirements defined on real / feasible needs

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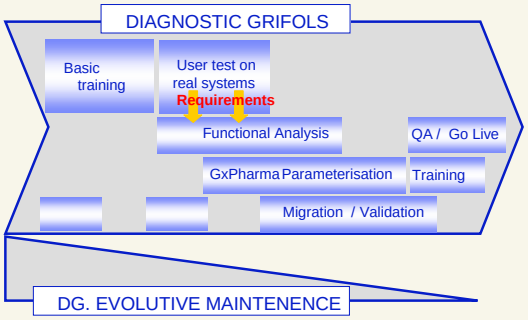
What has been done?: the approach

- Global approach for the implementation:



- Basic training on DM on real systems
- Requirements from real experience
- Evolution on real / feasible requirements

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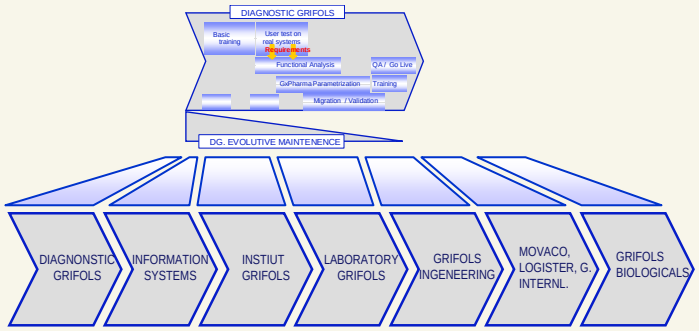
What has been done?: the approach

- Same approach for all the companies in the group:



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What has been done?: Quick implementation

- Quick implementation:
  - This would allow users to work with the **solution** ASAP and re-adapt their Document Management Procedures
  - This would provide the final user with a **faster and higher satisfaction and involvement**
  - This would allow a **pattern** to be replicated

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What has been done?: Roll-out approach

- Roll-out approach:
  - Following companies **would adopt the system** while leveraging previous experience
  - **Cross-company issues** temporarily managed and kept in background for a global approach

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What has been done?: Configuration vs. development

- Configuration vs. development:
  - Configuration is much **easier to migrate/maintain** than custom development
  - Minimising development minimises “reinvention” of the wheel for every company to be added to the system
  - Configuration decreases time of implementation

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What has been done?: real & feasible needs

- Requirements settled on real / feasible needs :
  - Users testing the system in a **short time** (days) would allow identification of requirements based on real systems
  - Real systems provide **deeper knowledge** thus fitting requirements to real needs
  - Real system knowledge allows a more **feasible / realistic cost-benefit analysis** when prioritising requirements
  - Workshops will allow users to **manage expectations** according to system capabilities; therefore, **change management** is kept simple

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Benefits

- Contents:
  - Introducing the actors
  - What has been done?
  - Benefits
  - Lessons learned
  - Still in route

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Benefits

- Quick pattern for a company in the group after 14 weeks
- Leverage of real experience in every company to be added to the system
- Implementation time reduction, means cost reduction
- Regulatory compliance from an out-of-the box approach
- System and data integration with ERP and CAD
- Audit Trail
- Simpler tools both for Document and Product Lifecycle Management

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Benefits

- Quick pattern for a company in the group after 14 weeks

  - Any custom development trying to achieve the same scope would have led to a much longer timescale
  - 14 weeks included system validation thanks to the Validation Package provided by GxPharma
  - Quick implementation, small team: 5 consultants

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Benefits

- Leverage of real experience in every company to be added to the system

  - Accumulated functionality on finding out new requirements; leveraging what others have already discovered
  - Requirements list shortened at every roll-out, this means, shorter time and smaller teams for subsequent roll-outs

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Benefits

- Implementation time reduction, means cost reduction

  - Out-of-the box functionality and packages (implementation, validation and migration) directly implies time reduction

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Benefits

- Regulatory compliance from an out-of-the box approach

  - Regulatory requirements for FDA (21 CFR 11) compliance already provided to be configured; no time for identification and definition
  - Roles, life-cycles, workflows and templates already provided from an out-of-the box approach
  - GxPs and ISO guidelines also considered

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Benefits

- System and data integration with ERP and CAD

  - GxPharma provides Compliance for all documents while they remain available from SAP GUI
  - Technical maps developed using CAD tools stored at a Documentum docbase
  - SAP integrated with CAD tools (ProEngineer)
  - Unique access point for R+D users for them to design
  - Documents linked to SAP transaction in the same way than SAP Data (materials, product codes, …) so document properties treated as SAP product information
  - SAP Data integrated with GxPharma to avoid typing errors

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Benefits

- Audit Trail

  - Audit trail implementation with no configuration needs
  - Electronic signature provided with no configuration needs

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Benefits

- Simpler tools both for Document and Product Lifecycle Management

  - An integrated environment provides a simpler way to find, manage and link information
  - Manual workflows for edit/review/approvals are eradicated
  - Information typing is minimised to reduce risk and errors
  - CAD designs automatically exploited in SAP and technical maps managed by Documentum

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Lessons learned

- Contents:
  - Introducing the actors
  - What has been done?
  - Benefits
  - Lessons learned
  - Still in route

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Lessons learned

- Roll-out approach requires correct ordering of companies
- Document Management expectations are not always clear from the beginning. This impacts on timescales if user satisfactions wants to be achieved
- Regulatory requirements are not usually known or agreed in the same way in a company
- Integration success requires skilled teams from all parties
- Things are not always as straight forward as they seemed in a beginning, plan for this
- Implementation + evolution; the correct approach

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Lessons learned

- Roll-out approach requires correct companies incorporation plan

  - Previous analysis is advised in order to check which company in the group goes first in the roll out plan
  - This will guarantee roll-out feasibility

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Lessons learned

- Document Management expectation are not always clear from the beginning impacting on timescales if user satisfactions wants to be achieved

  - Not all final users need to be Document Management Experts
  - Do not assume that one size will fit all
  - Reasonable timescale and change management should be agreed

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Lessons learned

- Regulatory requirements are not usually either known or agreed in the same way in a company
  - Although regulation restrictions are well-known by final users, the impact of the restrictions on Document Management may not be well known
  - Differing level of understanding in different places in the same company for the same point in the regulation can be experienced. Here is were we can help to unify criteria

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Lessons learned

- Integration system require not only Document Management skilled staff
  - Integration is a peer-to-peer matter
  - SAP is not Documentum; Pro/E is not Documentum
  - Documentation is used to provide information about concrete products; it does not always explain all you need about integration
  - Provider support is absolutely required

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Lessons learned

- Things are sometimes not so simple as they seem in a beginning

  - Documentation guidelines can change within an implementation as a project experience will not simulate the original testing environment
  - Efforts and a schedule must be checked regularly, and if needed, double-checked in favour of both parties

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Lessons learned

- Implementation + evolution; the correct approach

  - Users do not need to eternally wait to “see something”
  - Evolution based on real experiences is a successful implementation
  - Evolution should be limited in scope; everything cannot be postponed to a “second phase”

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Still in route

- Contents:
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  - Still in route

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Still in route

- Finalizing the implementation of SAP PLM integrated with Documentum (GxPharma)
- Spreading around the group (Grifols) adding companies onto the system
- Planning to help Probitas Pharma to roll-out their Document Management System to their partners in the States
- Helping Probitas Pharma in other Document Management initiatives
- Planning to help Probitas Pharma to evolve their Documentum/GxPharma systems as Documentum does

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More information at

- www.ibm.com/industries/lifesciences
- IBM booth # 5
- Thursday 13th May – Track 4: "*Achieving accelerated Deployment Success with GxPharma 5*" (Rik Van Mol)

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MANY THANKS !!

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