IT Vision : 2018 - 2020
way forward

atanu bhaumik

1st Cut (04-Apr-2018)

2nd Cut (16-Apr-2018)

3rd Cut (28-May-2018)

PRISM
adding life to living...

SAP or NON-SAP …
(Naturally SAP – Why ?)

Solution Selection

- The year 2018-22, good opportunity for Pharmaceuticals, hence our solution has to be scalable and should have a built-in-capability to support us for next 5 years minimum, with out getting in change. Customization is as-and-when needed.
- SAP is the only one as per the Best Practices for Pharmaceuticals & designed to meet these challenges – faster and more efficiently.
- A visionary organization like Prism requires a robust integrated Enterprise Resource Planning (ERP) system. SAP's solutions allow for a complete transformation – to move from slow to fast.
- An integrated ERP system from SAP will provide the backbone support for us amongst other pharmaceuticals companies, where it will provide end to end integration for various back office functions; beginning with Finance, Sales and Distribution, Material Management, and moving on to Production Planning and Business Intelligence…

V I S I O N
I . T .

PRISM
adding life to living...

VISION I.T.

SAP Modules

Financial Accounting (FI)

- General Ledger
- Accounts Receivable and Payable
- Fixed Asset Accounting
- Bank Accounting
- Cash Journal Accounting
- Inventory Accounting
- Tax Accounting
- Accrual Accounting
- Financial statements

Management Accounting (CO)

- Profit center accounting
- Cost center and internal order accounting
- Project accounting
- Product cost accounting
- Profitability accounting
- Revenue and cost planning

Sales and Distribution (SD)

- Master Data (Products, customers, partner functions, pricing & conditions)
- Sales Order Management
- Pricing & Conditions
- Availability Check
- Delivery Processing (Pick, pack & goods issue)
- Billing
- Order-To-Cash cycle
- Returns processing

Material Management (MM)

Quality Management (QM)

- Master Data (Materials, Vendors, Purchasing Info Records, Source List, Pricing & Conditions, Batch Management and Batch Classification for selected materials)
- Material Requirements Planning (MRP)
- Purchase Requisitions
- Purchase Orders (PO)
- Inventory Management
- Invoice Verification

Production Planning (PP)

- Master Data (Work Center, Routing, Recipe, …)
- Sales & Operation Planning
- Master Planning
- Capacity Planning
- Material Requirements Planning
- Productions Order
- Process Manufacturing

Business Intelligent (BI) – Analytics

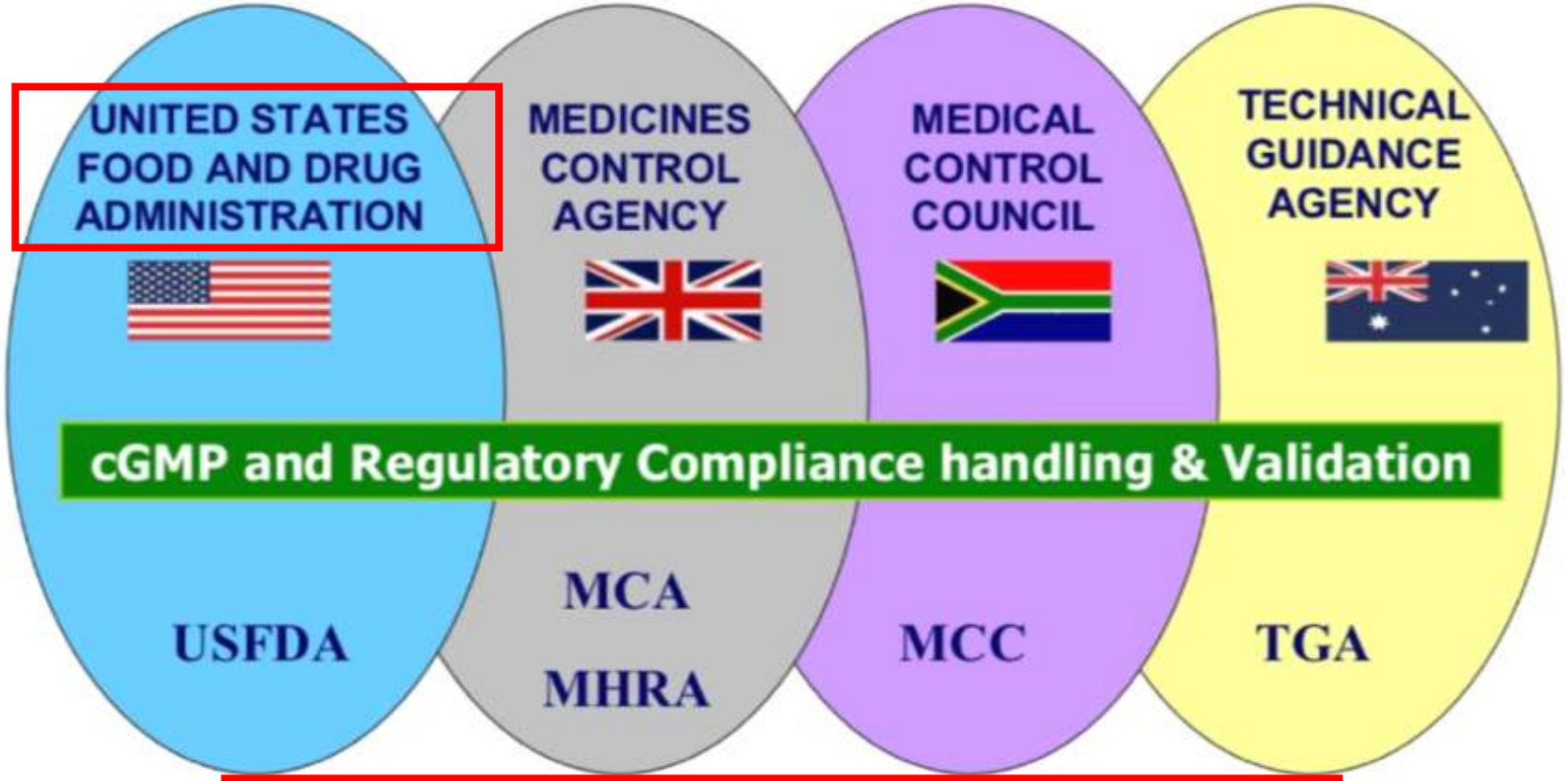
- Financial and Management Reporting
- Financial Planning, Budgeting and Forecasting
- Profitability Management
- Product and Service Cost Management
- Overhead Cost Management
- Payment Behaviour Analytics
- Working Capital and Cash Flow Management

PRISM
adding life to living...

International Regulatory agencies

WORLD HEALTH ORGANIZATION

GMP



Software compliance requirements for the above are the key features of SAP Best practices

Screen from SAP's PPT

VISION I.T.

PRISM
adding life to living...

Regulations in the pharma industry

21CFR

- GMP – Good Manufacturing Practices

  GMP outlines the regulations and guidelines within specific country for medical products manufactured in that country or imported from other countries

- USFDA 21 CFR – United States Food & Drugs Administration

  21 code of Federal Regulation :

  21CFR, Part 11

  FDA's Standards for the use of Electronic Records and Signatures as an equivalent and/or substitute for paper records and hand written signatures executed on paper

  21CFR, Part 210

  FDA's Current Good Manufacturing Practices in Manufacturing, Processing, Packing or Holding of Drugs;

  21 CFR, Part 211

  FDA's Current Good Manufacturing Practices for Finished Pharmaceuticals

VISION I.T.

PRISM
adding life to living...

21CFR

PONTERS FROM PREVIOUS SLIDE

A set of rules formulated by USFDS governing access, storage, retrival, control & security of Electronic Records

A set of rules governing security, control and use of Electronic Signature

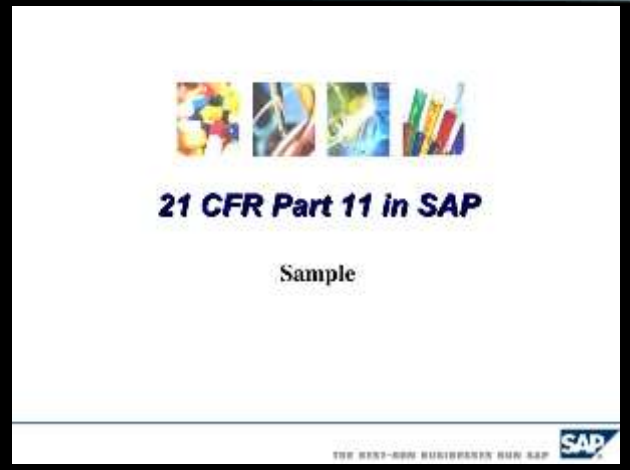
The basis by which Electronic Records and Signatures may be used as Equivalents to Paper records and traditional Handwritten Signatures

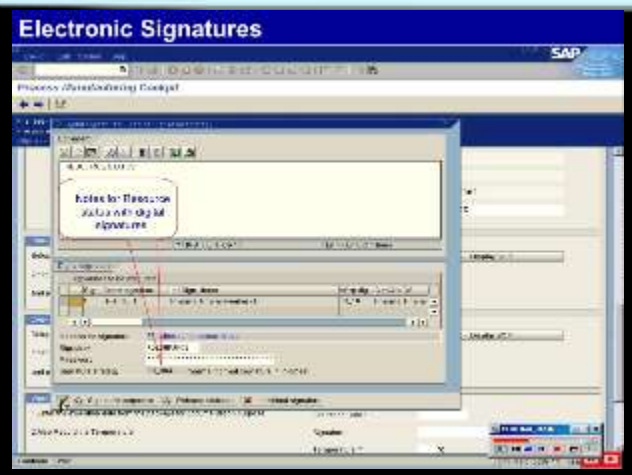
Examples of E-Records, what we need to watch for :-

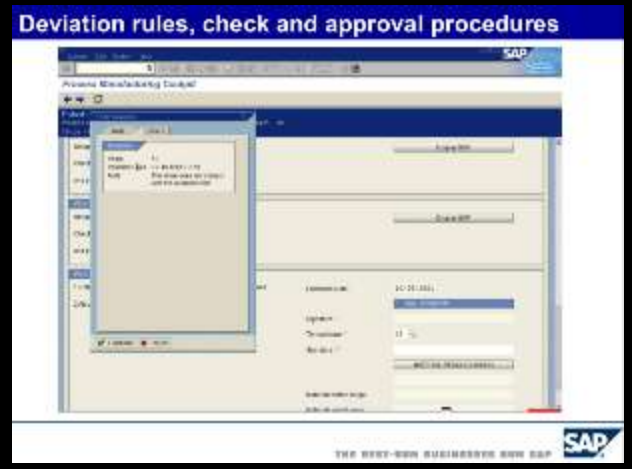
- Batch Records (Manufacturing Records)
- Compliance Records (Validation IQ/OQ/PQ Protocols)
  IQ stands for Installation Qualification. **OQ** is Operational Qualification and **PQ** is Performance Qualification
- Laboratory Data (Routine Inspection, Stability Sample Management)
- Manufacturing Data (Master Formulation record, Master Packaging record
- Training Records (cGMP 21 CFR Part 210, 211 & Part 11)
- Calibration Tracking Records (Laboratory Equipments)
- Audit Trails (Deviations Listing, Resource Logs)

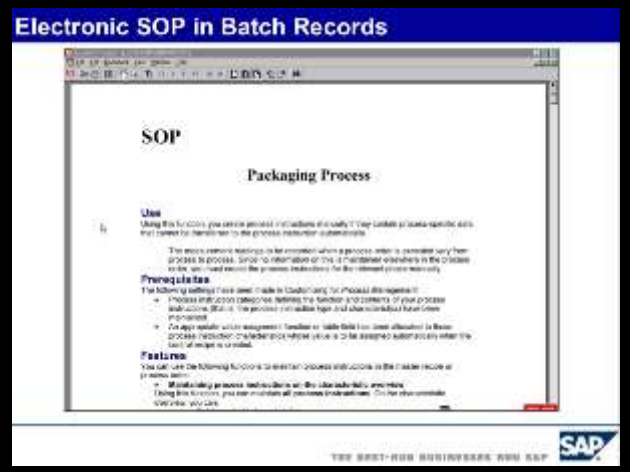
VISION I.T.

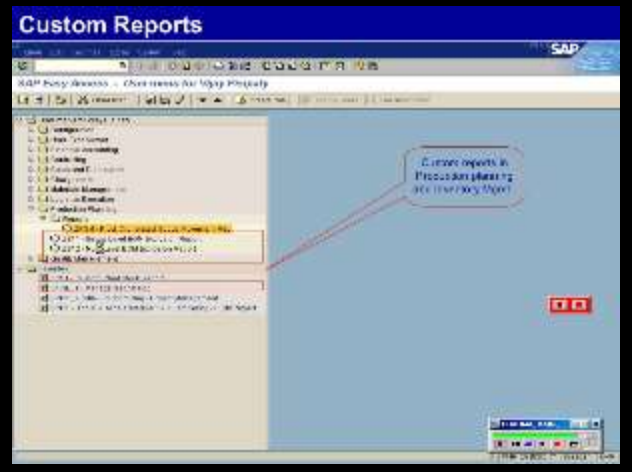
PRISM
adding life to living...











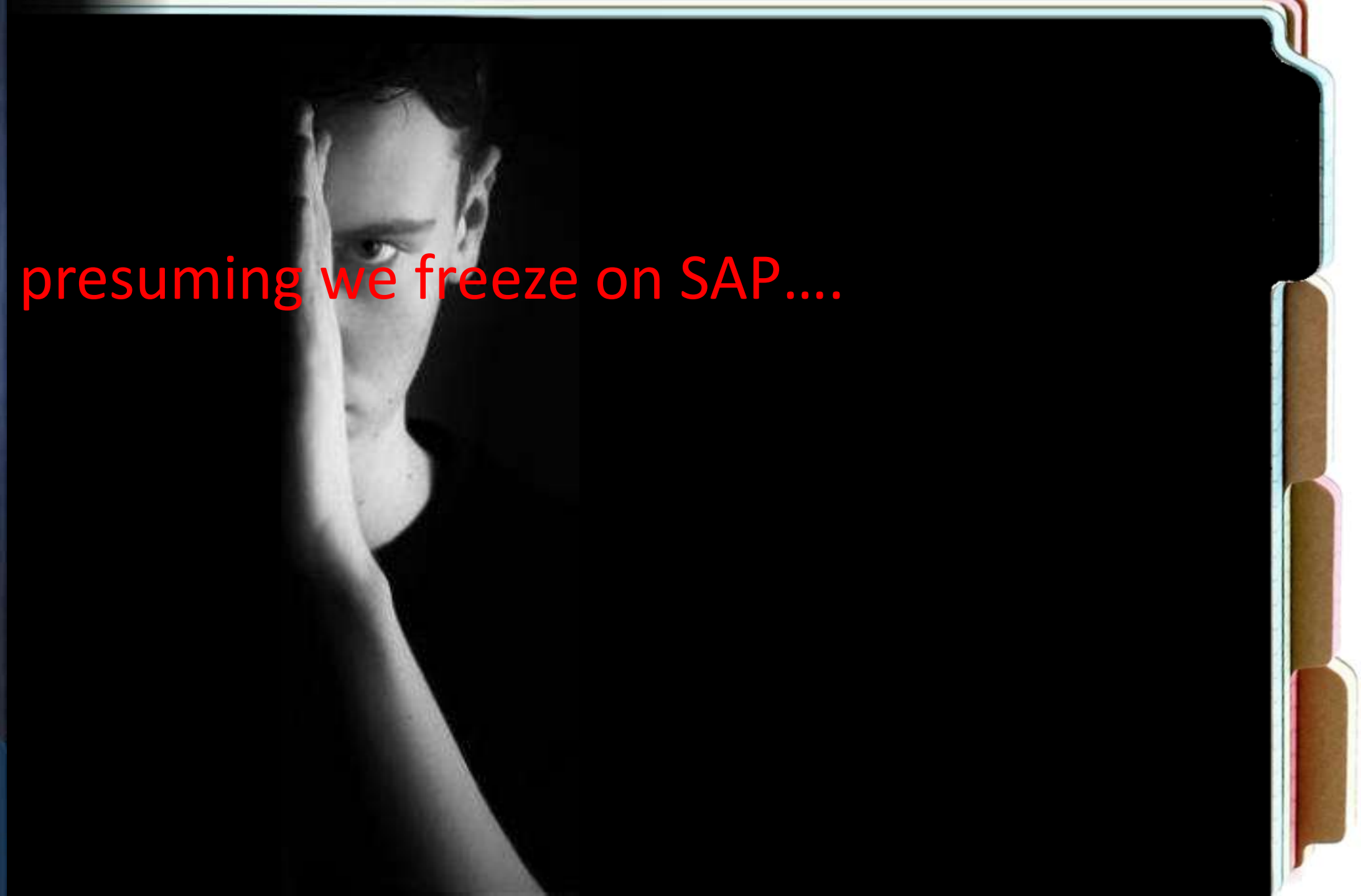
These are some of the slides, I could copy paste from the presentation of SAP; showing the actual app's screen, as an evidence getting convinced of the fact of SAP as an ERP, being compliant or non-compliant ...

Sample

VISION I.T.

PRISM

adding life to living...



presuming we freeze on SAP….

V I S I O N

I . T .

PRISM
adding life to living..

vendor selection

Indiba	rpm info
Expertized in Process Reengineering	21CFR part 11&12 implementation
Implementers of ISMS and ISO standards, can get us IPO listed	Exposure to US Laws
Next to our office & already has an agreement with Toolyt	Multiple Pharma installation
Comes in with Finance & Pharma Shop floor Expertise	

V I S I O N
I . T .

PRISM

adding life to living..

Recruitments plan shared ..

V I S I O N

I . T .

PRISM
adding life to living...

Roll Out

(1st which vendor) ….

Usually it's a 4 major steps [each step is further broken]

1) Interviewing Functional Heads to know how they actually do their part of work.
2) Process gaps are identified – if need be the existing process is reengineered/improved.
3) Set up a process for Gap analysis, implementation and Data migrations along with timelines and responsibilities.
4) Get extensive training before rollout – clear doubts and "corrections & preventions" noted.

Go live – 13th Week (around 15th Aug., provided 25th Jun. rolls-out as planned)

VISION I.T.

PRISM

adding life to living...

Next is the comparison, just for an idea ….

V I S I O N

I . T .

PRISM
adding life to living...

comparison

	Score	Justification	Speciality	21CFR Expertise	Scalable	Support	Budgetary Cost
Indiba	A	Demostrated capability of implementing in Indian Scenarios and already interacted with our HODs & hence respective comfort. Plus the flexibility and acceptance towards quick requiement. We shall be able to manage the surprises with them.	SAP B1 + Machine integration	A+	Always, usually it's add-on at an incemental cost. All addins are SAP released and hence tested.	Best and immideate Support expected, as they are next to our office. And also has been available in our office in 15-20 minutes when we called.	18 Lac
Batchmaster	C	Very close to our present requirement, but not scalable with our speed of growth	Rx App	B+	No, Not till New Version Released or customised.	Pune Based	20 Lac
Progen	D	Seen the demo - good for present requierment, but scalability isnt visible	Rx App	B+	No, Not till New Version Released or customised, every customisation will need to be tested and it will be a cause to slow-down business	Mumbai - Malad	12 Lac
RPM infotech	B	Demostrated Capability of implementation in US. Procedure ordiented. Highly professional and looking at the fact that our HODs are not conversant with their requirements, hence Sure to have gaps post the implementation due to rigid & professional outfit.	SAP B1	A+	Always, usually it's add-on at an incemental cost. All addins are SAP released and hence tested.	Mumbai - Mulund	

V I S I O N
I . T .

PRISM
adding life to living...

The infra will be suggested … (in case its SAP)

Infra

- Main cost component :
  - The server Box – Xeon E5; providers are Dell, HP, Lenovo & Cisco; average cost 1.5 Lac rack mount
  - The SQL Database, we will use the MySQL, its free, instead of the MS-Sql with is around 50 k.
  - Operating System – Server 2012 Licenses, its costing around 50 k.
- Allied cost component :
  - CALs – this are the Client Access Licenses used to access the server remotely, we might need some extra.
  - Some additional computers for the users, either as an upgrade or as a replacement.
  - Training and incidental expenses should be looked at as contingencies.
- The security aspect would have been already taken care.
  - Gateway Firewall - @ 50 k
  - AV and client site security – anything between @ 1000 to 5000 per user

VISION I.T.

PRISM
adding life to living...

awaiting a “get set gro…👀w”

VISION
I.T.