



DBMS Consulting Overview and OPA Support Solutions



Introduction

- Sunil G. Singh of DBMS Consulting, Inc.
- Specialize in Oracle Pharmaceutical and E-Business implementations and long-term support.
- Thanks to the OCUG for this demo/discussion opportunity.



Agenda

- Present an overview of DBMS Consulting
- Present an overview of DBMS Consulting's OPA Support solutions
 - OPA Administrations and DBA/SA Activities related to OPA
 - Global RDC Deployments
 - Strategic Remote Support and Outsourcing Guidance for
 - OC, TMS, SAE related CDM activities



Overview of DBMS Consulting

- Consulting organization specializing in OPA and Oracle E-Business Suite Apps 11i implementations.
- Specialize in migrations, installation and configuration, technical and functional support and customized training.
- Support can be either long-term on-site support or remote support on an as needed basis.



Overview of DBMS Consulting (2)

- Currently have a total of 10 Full and part time consulting staff
- Share administrative tasks internally to reduce costs
- Technically categorized as a Systems Integrator (SI) for OPA
- Maintain presence in New York, Southern California, New Jersey and India, through small offices or home offices

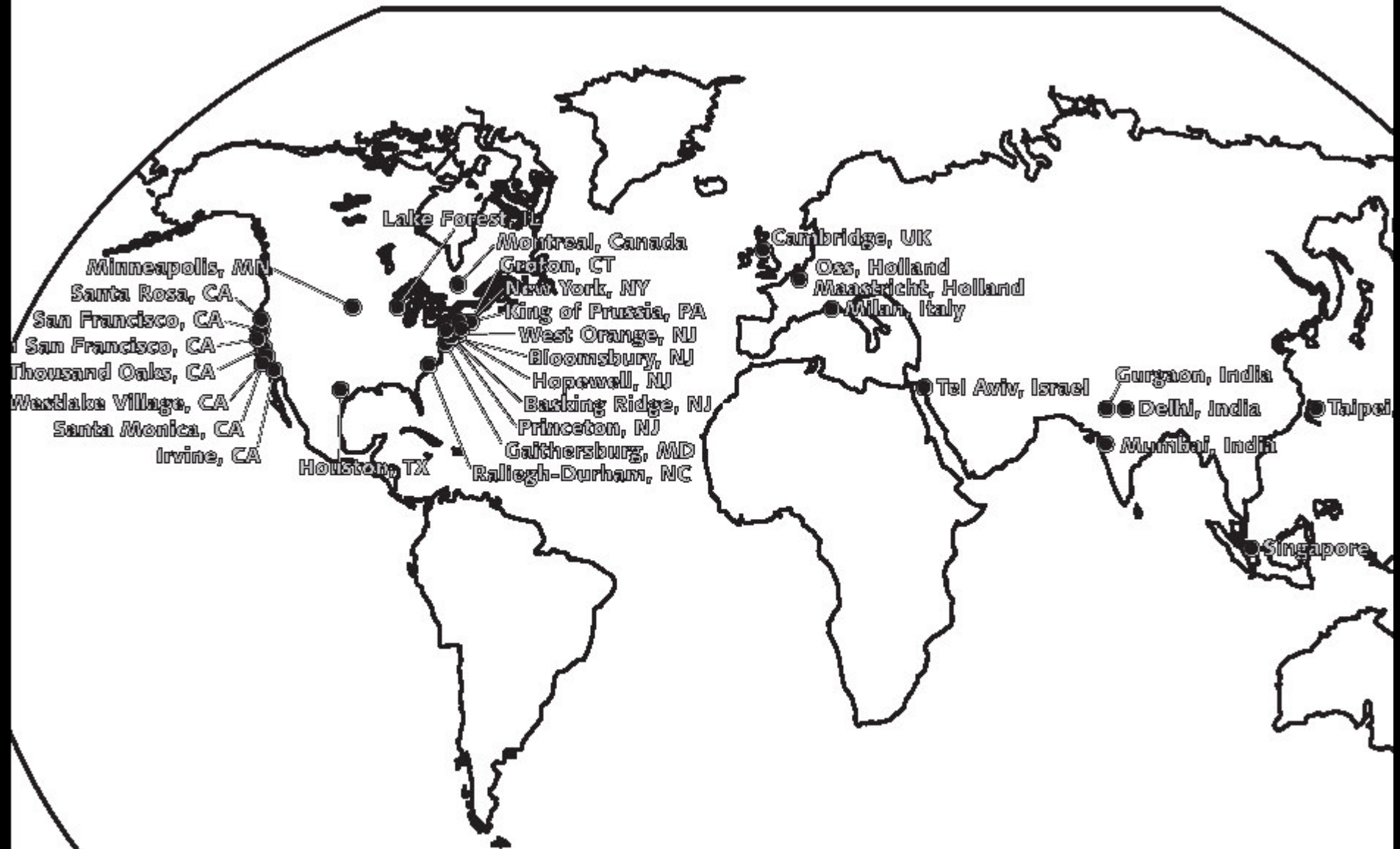


Overview DBMS Consulting (3)

- All full-time staff travel extensively to client sites and are usually on-call 24-hours.
- DBMS Consulting currently maintains a long-term presence in several companies.
- Additionally, 24 x 7 remote support and OPA Application Support Outsourcing is provided to several organizations.
- Total number of companies that have employed the services of DBMS Consulting for OPA related work is over 30, including CROs, Biotechs, Pharmaceuticals, Medical Device Companies and Academic Institutions



OCUG Baltimore 2005: DBMS Consulting OPA Support Services



Locations of DBMS Consulting's Successful OPA™ W



Overview DBMS Consulting (4)

- Alliance Member Partner of Oracle Corporation
- Channel Alliance Partner with Mercury Interactive
- DBMS is very price competitive and cost-conscious. Tremendous effort to reduce expenses to customers.
- Guarantee customer satisfaction on all work or no billing for that work.



Overview DBMS Consulting (5)

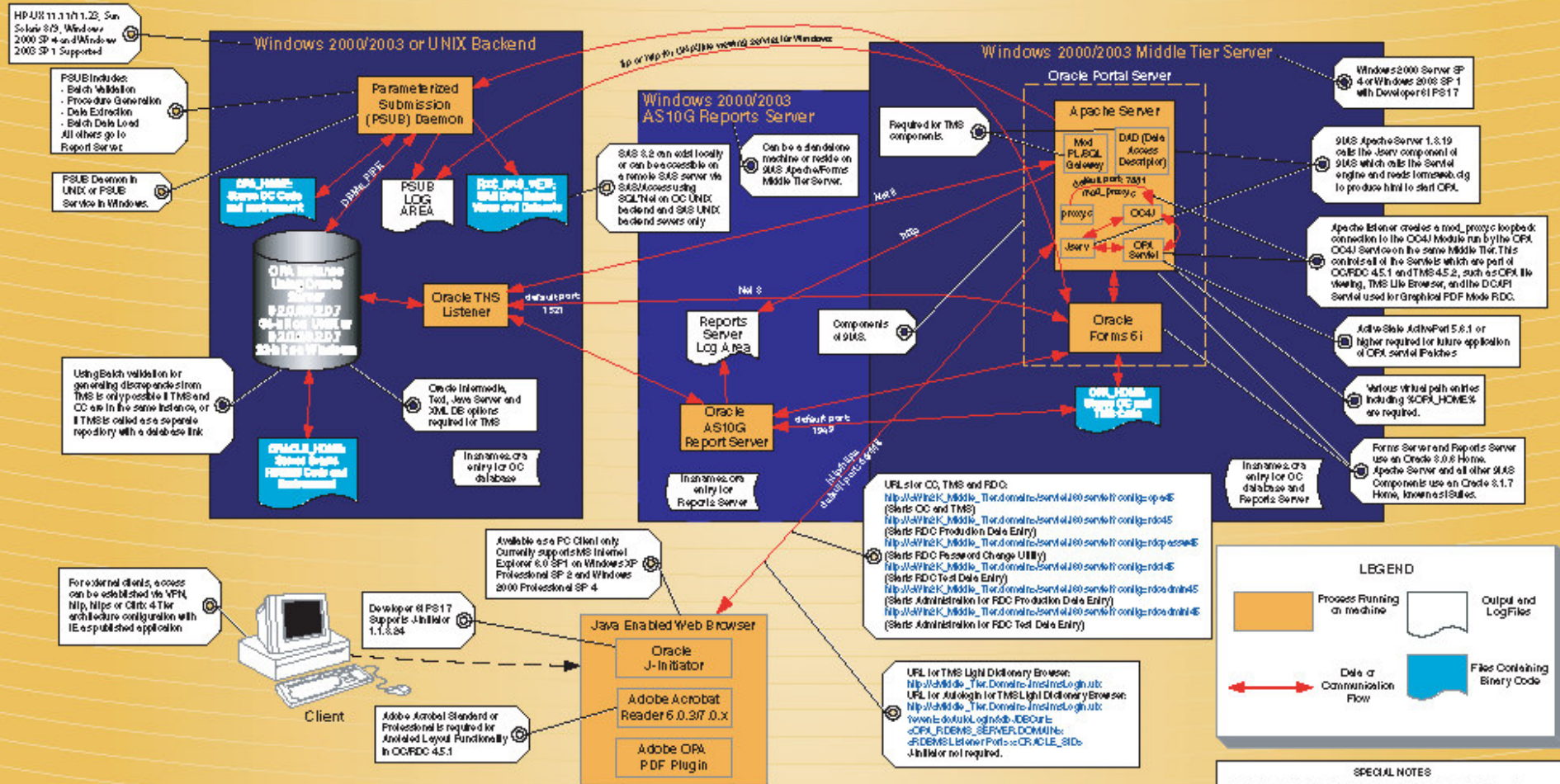
- Tremendous technical expertise in Oracle, with most members of DBMS having an Oracle DBA or Development background in either the Pharmaceutical or Financial sector.
- Typically, we are called to solve the most difficult technical issues or to offer strategic implementation advise.
- Created a series of architecture diagrams for the OPA to assist customers with the true understanding of OPA and the myriad configuration options available.



OCUG Baltimore 2005: DBMS Consulting OPA Support Services



OC/RDC 4.5.1, TMS 4.5.2 3-Tier Configuration



Get Global OC Done. Right.

US Headquarters: 1173 Second Ave STE A PMB 181 New York NY 10021 USA • Phone 888.757.8819 • Fax 212.208.4618 • Pager 888.468.4751 • Web <http://www.dbsm.com>

Additional copies of all architectures are available at www.dbsm.com. Retail value: \$25 USD. All products mentioned are trademarks of their respective companies.

© 1999 - 2005 DBMS Consulting, Inc. Any unauthorized duplication or reproduction of this work by any means is strictly prohibited by federal and international laws without permission from DBMS Consulting, Inc.

Any violation of this copyright protection will be prosecuted to the fullest extent of the law.



Overview of DBMS Consulting: Management Consulting (6)

- Provide detailed Management Consulting, Process Re-Engineering Support, and Strategic Direction/Insights answering key high-level management questions for current and potential OPA customers such as:
 - How do we cost justify implementation of OPA?
 - How do we measure ROI when implementing OPA?
 - Developed a set of key metrics for use against legacy systems to compare Data Entry, Data Management, time to analysis, time to reporting and submission, and Medical coding metrics to quantitatively measure costs and ROI, as well as intangible factors
 - What process re-engineering is required to deploy an EDC/RDC solution?
 - Developed a 16 step process for deploying and implementing RDC



Overview of DBMS Consulting: Management Consulting (7)

- How do we choose a strategic partners for OPA?
 - Hardware and Network Systems Vendors
 - CROs
 - Data Management
- How do we cost-effectively capitalize on emerging trends in Outsourcing model?
 - What is the value of an outsourced and/or off-shore model?
 - What activities should be outsourced ?
 - Should we develop “outsourced” centers internally ?
 - How do we choose an off-shore partner? What do we look for? What questions should we ask?
- How do we get the most value for the time and money we have spent on OPA?



What are the Advantages of DBMS Consulting over larger OPA Service providers?

- Personalized attention and direct access to all resources who can help with a critical issue (“flat team approach”).
- Access to direct knowledge of other real-world implementations and issues.
- Willingness to share useful information, and to contact other resources as well as other customers to find solutions.
- No interest in sales of a product or pre-defined sales quota. An objective evaluation of OPA’s strengths and weaknesses at all times. (“honest broker”)
- Tremendous flexibility in cost negotiations, discounts, long term and deferred payments with consideration to customer’s budgets.



Other OPA-Related Products and Services

- OPA Support Services and OPA Support Outsourcing Services
- Validation Services and Materials for OPA, including OC, TMS, RDC, and AERS
- Standard and complex Custom development for OPA (Menu Roles, DCFs, to integration with other legacy systems)
- TMS Autoencoding development, from standard to complex search objects and external system integration
- Flat-rate customized functional and technical OPA training.
- Partnership with the WHO-UMC to develop certified loading and update scripts for all WHO dictionaries for TMS, including updating WHODrug Type B to WHODrug Type C Dictionaries already loaded in TMS.
- Technical recruiting for Oracle-related requirements
- Customized automated testing development, using Mercury Interactive toolsets.



DBMS Consulting's India-based Activities

- Started DBMS Consulting India, Private Limited based in New Delhi supporting India and Asia-based OPA customers, in a reverse outsourcing/reverse off-shore model
- Provides all aspects of implementation expertise and long term support for several Oracle Pharmaceutical Applications customers
- DBMS Consulting is currently engaged in two OC and RDC 4.5 pilot studies in PDF Data Entry mode in India for India-based Pharmaceutical and CRO companies
- Developed the knowledge of the OPA industry players in India, and have direct and first-hand experience on the major service providers in the region, as well as the local and regional regulations, environmental and infrastructure factors and politics which will greatly influence any decision for a company to perform work in India



DBMS Consulting's Experience in OPA Support

- DBMS Consulting already provides OPA Support on an on-call 24 x 7 basis to several companies.
 - CROs which demand real-time support but can not afford on-site consulting resources
 - Medical Device companies where assistance for on-line OPA support and ad-hoc SQL reporting
 - Large Pharmaceuticals with broadband VPN access that provide laptops for connectivity into their environments where on-site support staff may not be available
 - Large Biotech companies which need both Oracle DBA and Oracle OPA support
 - Asian based Pharmaceuticals and Government Institutions which have limited OPA support in their time zones.



Why seek help with OPA Support outside of Oracle?

- There are gaps in the level of support currently provided by OPA
 - There is a need for immediate assistance with complex OPA related issues “Need an answer now Gap”
 - Global users do not have support from OPA for customizations “OPA Customization Gap”
 - There is no direct access to OPA development through OPA Support “Developer access Gap”
- OPA is constantly in a development and deployment mode. Unlike other applications which reach a “plateau of stability”, the nature of OPA requires that there is an ongoing cycle of
 - Request for changes, enhancements, bug fixes, or maintenance upgrades/patches
 - Validation
 - Deployment
 - Training



Why seek help with OPA Support outside of Oracle? (2)

- OPA Customers are examining methods to **reduce the support and maintenance costs of all of its large applications**, which includes OPA, as well as operational costs overall. This is an industry trend for all global companies across all sectors, not restricted to only Pharmaceutical companies
- Many OPA customers have already developed a huge internal support infrastructure with so many parts and pieces. Running this internal support organization, coordinating and routing issues, and sharing the knowledge and expertise across all parts of the organization is a difficult task, which itself has management and overhead costs associated with it.
- Some OPA customers have a huge internal support infrastructure, which may be performing redundant tasks globally



Why seek help with OPA Support outside of Oracle? (3)

- OPA Customers are Pharmaceutical/Medical Device/CROs, not IT Service Providers and not Application Support Providers
 - OPA Customers have strategically aligned themselves with Oracle in the concept of OPA as a Commercial Off-the-Shelf (COTS) system.
 - However, many OPA Customers find themselves in an ever increasing role to support and maintain all various aspects of OPA, from routine maintenance of user accounts and security, to formal or de-facto testing new enhancements and functionality on behalf of Oracle.



Remote OPA Administrations and DBA/SA Activities related to OPA

- Provide support to OPA System Administration in real time basis, using
 - VPN Connectivity
 - On-Line Connectivity (e.g., Web-Ex, NetMeeting)
 - Phone, e-mail and IM Connectivity
- To connect directly into customer's sites and work directly with OPA Admins, DBAs/SAs
- Provide "call queues" to reach someone on a 24x7 basis
- Provide assistance from Reference Codelists, back-end configuration, /etc/system, http.conf, bc4j.xcfg, to Oracle RDBMS to Win2K/2003.



Remote OPA Administrations and DBA/SA Activities related to OPA (2)

- Perform major tasks, such as
 - OPA migrations,
 - character set conversions,
 - database/instance cloning,
 - middle tier rebuilds
- Provide remote system testing/stress testing and simulate user testing for public facing systems



Support for Global RDC Deployments

- Provide on-call support for sponsors of Global RDC studies using the same methods provided for DBA and SA support (VPN, On-Line, Phone, e-mail, IM)
- Provide a backup level to existing or planned implementation of user and site support desks, where specific or more difficult calls are routed directly to DBMS Consulting, and one-to-one support directly with users is provided
- Provide training and simulations for internal/external RDC Help desk to reduce “ramp-up” time for global deployments
- Provide strategic consulting for choosing large call centers and help desk providers, or
- Manage large RDC Help Desk and Support Centers through DBMS Consulting’s strategic alliances.



Support for Global RDC Deployments

- Work with specific sites which have connectivity or application related issues
- Facilitate and liaison with specific sites Network and Desktop administrators to resolve specific RDC related issues
- Provide strategic planning for implementation of long-term and immediate RDC support



CDM related Support

- DBMS Consulting provides remote development services for any OPA application related activity:
 - Study Design and Development
 - RDC Graphical and Classic Mode pilot studies
 - Legacy or paper based studies migrated to OC/TMS/RDC
 - Validation/Derivation Procedure Development
 - DX view configuration and testing
 - AERS Workflow Configuration and testing
 - TMS Dictionary Loading and Domain configuration



CDM related Support (2)

- We provide training for either internal or outsourced centers performing Data Entry, Medical Coding, and SAE management
- We provide strategic consulting to help companies identify and qualify outsourcing or build internal CDM support
- We provide large scale outsourcing solutions through DBMS Consulting's partners to perform this activities on an outsourced basis also.



CDM related support (3)

- Provide guidance into building “internal” support centers based in India
 - How to cost justify this model
 - How to locate and identify qualified resource
 - How to reduce turnover ratio
 - How to protect intellectual property
 - How to provide regulatory compliance
- Provide strategic training and management guidance for the internal centers
- Provide back-up level support for these internal centers



Q&A.

- Please come to Vendor booth 8 & 9 with any additional questions and more detailed demos
- Also for more Brochures, posters and business cards and mini-mice

