

The Doors Beyond Clinical Data Management

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Who We Are....

- The Leader in Information Technology Support and Services for the Clinical Research Environment
- Headquartered in Pottstown, PA
- Solutions include Services and Software Products
- Three Business Lines:
 - *Clinical Systems Services (CSS)*
 - *Clinical Reporting Services (CRS)*
 - *Computer Systems Compliance Services (CSCS)*



Who We Are....

- **Expert Consultants**
 - *Clinical Research Business Process*
 - *Project Management*
 - *System Selection, Development, Implementation & Support*
 - *Systems Validation*
 - *Migrations*
 - *Programming*
 - *Database Administration*
 - *Training*
 - *Regulations, e.g. GXPs, 21 CFR Part 11*
 - *Standards, e.g. IEEE, CDISC*
 - *e-Submissions*





How do we see ourselves?

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How do we see ourselves?

- Organizational expert
- Communications and mediation expert
- 21 CFR Part 11 expert
- GCP expert
- HIPPA expert
- Oracle DBA
- Hardware and Software Systems Administrator
- SQL Programmer



How do we see ourselves?

- Make a list of all the different things that you do in a typical month, in a quarter, in a year.
 - Do you program complicated edit checks requiring SQL programming?
 - Do you perform backups of the clinical database?
 - Do you settle 'disagreements' between Data Management staff and Biostats or Clinical Ops?
 - Do you perform manual AE and ConMed coding?
 - If something goes wrong with the server, who trouble-shoots the issue and contacts the appropriate manufacturer support?



How do we see ourselves?

- Make a list of all the different things that you do in a typical month, in a quarter, in a year.
 - Do you create the analysis datasets before you send them to Biostats using SAS?
 - Do you program edit checks in SAS?
 - Are you responsible for the departmental budget?
 - Do you manage staff? Are you responsible for annual reviews, disciplinary actions, promotions, raises? Hiring / Firing?
 - Do you provide project progress reports to upper management?



Write it down





Write it down





Enjoyment and Career

■ What part of your job do you enjoy the most?

■ Where do you want to be in 5 years, in 10 years?



Enjoyment and Career

- Do these two questions have conflicting answers?



Goals and Actions

- If the answers conflict, then do the following exercise:
 - First, you have the list of all the things you do.
 - Take that list and pick out the things you like to do.
 - Rank the things you like to do (1 for the activity you enjoy the most, 2 for the next, and so on)
 - Take the top 5 or so activities, and identify what about those activities you enjoy (working with people, managing the big picture, writing code, whatever)
 - Hang on to the list of activities, you will use this again later



Goals and Actions

- If the answers conflict, then do the following exercise:
 - Start another list of what is important to you (family, financial security, career growth, etc) and rank these items
 - Take a look at the list of activities and the list of what is important and see how they match up – this will help direct your career decision making
- Do not expect this to be an easy or short exercise, it may take you 3 days, it may take you 3 weeks – it will take as long as it takes



Possible Directions

- If programming or database administration tickles your fancy then, becoming a
 - Statistical programmer
 - SAS
 - Masters in Statistics
 - Oracle DBA
 - Oracle DBA certification
 - Additional course work
 - Computer systems or network administrator
 - Advanced degree in computer programming / system admin



Possible Directions

- If project management is exciting to you then, becoming a
 - Clinical Project Manager
 - CRA experience or knowledge
 - Some kind of project management certification
 - Demonstrated job experience
 - Program Director
 - RN or MD degree
 - General experience in clinical operations (CRA, DM, drug development, etc)



Possible Directions

- If people management is what trips your trigger then, becoming a
 - Director or VP Clinical Data Management
 - Advanced degree (MS, MA), RN or MD degree
 - Budgets
 - Management of large number of persons
 - Knowledge of company organization and politics
 - Ability to negotiate and compromise
 - Ability to develop staff
 - Ability to rally staff to meet emergencies or shortened deadlines

Possible Directions

- If you find the regulations fascinating and understandable then, becoming a
 - Validation Expert in Regulatory Affairs
 - 21 CFR Part 11
 - FDA compliance issues and direction of enforcement
 - Company's level of risk
 - Industry standards
 - GCP Compliance Officer
 - GCPs
 - Ability to get people to do what they are supposed to do, not what they want to do – and still remain on good terms
 - Company organization and politics
 - Company's level of risk
 - Industry standards



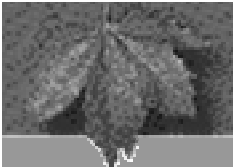
Possible Directions

- If you find the regulations fascinating and understandable then, becoming a
 - Regulatory Associate
 - GCPs, GLPs, GMPs, HIPPA
 - Ability to get people to do what they are supposed to do, not what they want to do – and still remain on good terms
 - Company organization and politics
 - Company's level of risk
 - Industry standards
 - FDA compliance issues and direction of enforcement



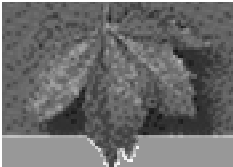
Possible Directions

- Do you need more training?
 - DIA
 - RAPs
 - Oracle
 - Private companies
 - Night school
- Be creative
- Try on the hat before you buy it to make sure that the job fits



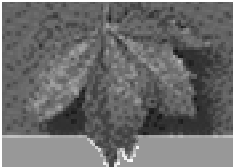
Conclusions (or Beginnings)

- You may not be able to jump into the job you want without going thru a few other jobs to get there
- This is the long look, you will not get immediate gratification from this process
- It will be frustrating and at time you will feel like you have impossible walls to get over, around or break thru – keep at it – persistence does pay off
- If you are changing careers, you may have to ‘pay your dues’ again (lower/lateral position, lower pay)



Conclusions (or Beginnings)

- You might be able to get experience in place of an advanced degree – check it out before you go back to school
- There may be other ways to get the education you need – conferences, Oracle DBA program, etc.
- Politics and policies may be one of the walls you need to surmount, find someone in your company that believes in you and will help



Conclusions (or Beginnings)

- Remember, this is an important decision. Take your time to find the right career path for you. Listen to advice from others, but follow your own heart and head – you will be the one that has to live with the decision, not any one else.
- Look for opportunities, take on extra responsibilities, help out in a crunch, these are things you can do to prove yourself
- Be patient and kind with yourself, this is a life-long process