KEY DIFFERENTIATORS FOR LIFE SCIENCES ORGANIZATIONS SUPPORTED BY QAD ENTERPRISE APPLICATIONS

1. The system will be able to be implemented to comply with 21 CFR Part 11
2. The system will be able to perform electronic signature approval of GMP related activities such as Work Order processing, Quality actions, Product movement and Product attributes.
3. The system will have Audit Trail capability to trace which user or individual changes critical data elements, such as PO data, Item Master Data, BOM and Formula relationships, etc.
4. The system will be able to support Process, Discrete and Repetitive manufacturing
5. The system will be able to handle Formulas and Bills of Materials
6. The system will be able to handle the manufacturing of pharmaceuticals, biologics, and devices
7. The system will be able to manage kits
8. The system will provide control over lot/serial assignment, with the ability to assign lot groups for auto lot number assignment
9. The system will be able to track both lot and serial number for a batch of serialized units
10. The system will be able to assign lot or serial number of individual components and to track those components through the entire manufacturing process
11. The system will support Serialization, at the unit, case and pallet level
12. The system will be able to record “as built” information
13. The system will be able to produce a device/batch history record
14. The system will be able to track lot and serial numbers from raw material receipt to the end user customer
15. The system will be able to support a recall
16. The system will be able to assign and track standard characteristics such as: Assay %, Item Status, Receipt Status, Inventory Status, Expiration Dates
17. The system will have ability to track extended item attributes, enabling users to define item-level lot or serial specifications to track attributes for documentary or quality control purposes
18. The system will be able to manage customer and supplier consignment inventory
19. The system will be able to handle Service and Support including Call Management, Installed base functions, field Service Engineer Scheduling, Contract and Warranties Management, RMA, RTS functions and Material Orders for Field functions
20. The system will be able to manage installed base information for devices, including repairs, warranty, extended service contracts, call activity, deport repair, and field service repair
21. The system will be able to generate Installation and Preventative Maintenance events for installed devices
22. The system will be able to allow for the creation of Routings / Processes based on Run Time/Batch Qty, along with Yield calculations for cost and CRP

23. The system will be able to manage both Master Schedules and detailed Production Schedules
24. The system will have a Capacity Requirements Planning Module which provides a complete picture of the Capacity required to produce the plan, along with over and under capacity constraints
25. The system will be able to check for resource capacity and component availability to ensure that production schedules can be achieved
26. The system will be able to handle Entity, Site, Menu and Field security ensuring that only authorized individuals can make changes to meet SOX compliance
27. The system will have the ability to have configurable screens and the ability to add user-defined fields to capture additional data
28. The system will have the ability to easily access data, such as production, sales, purchasing and quality activity with browse capabilities
29. The system will have a purchase requisitioning system which allows approval level points, such as, by product line, projects, organizationally or by specific jobs
30. The system will to able be able to manage an approved supplier list
31. The system will be able to report supplier performance based on user defined criteria, such as delivery date compliance, shipment completeness and quality measures
32. The system will be able to prevent sales orders to regions and customers where product approval has not yet been granted
33. The system will be able to handle Engineering Change Control, putting the required change process under user control to ensure that changes happen only under validate-able conditions with the appropriate sign off
34. The system will offer an integrated Quality Management System
35. If deployed in the Cloud, the system will be deployed in a single tenant, FDA qualified environment
36. The system is used widely in the life sciences industry
37. The system will be supported by a software vendor with focus on the life sciences industry
38. The system will have vibrant user group communities
39. The system will have a robust product development roadmap
40. The system will come with a proven validation toolkit to enable rapid & efficient software validation
41. The system will include Life Sciences industry best practice process flow diagrams integrated to the ERP software
42. The system will include Life Sciences industry best practice ISO Level 3 compliant end-user desktop procedures