



Systems that support your compliance obligations

WHAT COMPLIANCE OBLIGATIONS

DO I HAVE TO MEET?

There are a number of key issues that impact on organisations in the pharmaceuticals and life sciences arena. High on the list is compliance with 21 CFR Part 11, including electronic signatures. The period of grace for part 11 compliance is now over, and the FDA now requires that all organisations concerned with process manufacturing for the pharmaceuticals and life sciences industry comply.

PART 11: THREAT OR OPPORTUNITY?

Some industry experts have estimated that the cost of compliance could run into many millions and Part 11 is often regarded as a threat. However, treat it as a business improvement process and it becomes a significant opportunity, enabling:

- reduced costs of data gathering
- improved production quality
- better data accuracy
- new data analysis opportunities

HOW CAN ORACLE PROCESS MANUFACTURING HELP ME COMPLY?

Oracle Process Manufacturing (OPM) will help your organisation to meet your compliance obligations in all the relevant areas, including:

- security (including passwords and access control)
- electronic signatures
- batch traceability
- audit trail
- validation support

It is the organisation not the application software that must comply with Part 11. So, whilst no software application can guarantee compliance, OPM provides a series of tools and mechanisms that will help your organisation comply.

ARE THERE ANY OTHER BUSINESS BENEFITS?

Compliance is only one item on a lengthy list of issues and drivers that influence the industry, these include:

- costs of bringing products to market
- Governmental intervention and control
- consumer influence
- increasing global competition
- recruiting and retaining talented people
- regional marketing strategies

Oracle can help you to deal with all of these and other issues that face your business. By choosing OPM, you will give your organisation the opportunity to build on its investment, and implement world class solutions for HR, financials, marketing, sales and supply chain management.



IS ORACLE RIGHT FOR MY ORGANISATION?

Oracle applications need not be complex or expensive. At Praktis, we specialise in delivering pragmatic solutions quickly and efficiently.

HOW WILL IT BE DELIVERED?

The modular approach of the Oracle E-Business Suite enables you to choose the modules that will help you to generate business improvement and deliver real ROI. Moreover, the fully integrated nature of Oracle's applications reduces implementation costs dramatically.

HOW CAN I FIND OUT MORE?

For further information, call Colin Grace on 01925 856161 or e-mail us at

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ORACLE CERTIFIED PARTNER

MAKING PERFECT SENSE OF E-BUSINESS