



CALIBRATION SOFTWARE SELECTION

Business Requirements

PRESENTED BY

 **IndySoft**

Regulatory Requirements

1

Is your system compliant to ANSI/ISO/IEC 17025:2017? If not, describe the gaps and your action plan.

2

Is your system compliant to Food and Drug Administration Quality System Regulation 21 CFR Part 820 Medical Devices; Current Good Manufacturing Practice; Final Rule? If not, describe the gaps and your corrective action plan.

3

Is your system compliant to FDA Title 21 Code of Federal Regulations (21 CFR Part 11) Electronic Records; Electronic Signatures; September 2003? If not, describe the gaps and your corrective action plan.

4

How do you support the validation of your software?

5

How will you support future revisions of regulatory documents?

6

How do you support assistance to your customers regarding audit findings due to system software gaps?

7

What is your method for handling customer recommendations for software system improvements or enhancements?

8

How does your system handle data validation?

9

How does your system handle audit trails and activity logs of all data changes?

10

Is your system Cloud based? If so do you have SOC 2 Type II certification?

BUSINESS REQUIREMENTS

Calibration Workflow

- 1 How does your system support automatic calibration interval adjustment? Will the system use the last calibration data results to activate a new cal interval to be reflected in the printed out calibration label?
- 2 Does your system support multiple scheduled maintenance services for each asset?
- 3 Does your system accommodate forward and reverse traceability with error checking?
- 4 Does your system accommodate individual time accounting entries?
- 5 How does your system handle on-line access to calibration and maintenance procedures?
- 6 Does your system automatically update due dates for preventive maintenance actions and other non-calibration services?
- 7 What is the limit of your open-ended history notes? Can history notes be searched?
- 8 How does your system ensure that the current revision calibration procedure is being used?
- 9 How does your system handle out-of-tolerance and non-conformance reporting and tracking?
- 10 How does your system handle bar codes and customized labels?

Calibration Workflow

11

What method is used to track and maintain equipment location?

12

Can there be data fields available for client access, read or write? How many?

13

How does the system accommodate the tracking of vendor services?

14

How does the system accommodate repair actions?

15

How does the system accommodate Preventive Maintenance management?

16

Is tracking of calibration standards accommodated to include reverse traceability? Describe the calibration standards management system?

17

Can procedures, pictures, graphs, spec sheets, schematics be attached to equipment records?

18

How is "as found" and "as left" measurement data handled?

19

Can "Certificates of Calibration" be printed out automatically upon completion of a calibration action?

20

Can technicians be assigned to user-defined groups for segregated work schedule, work flow, and work report tracking? How many different work groups can be defined?

Calibration Workflow

21

How are unique equipment numbers defined? Can there be different categories of equipment numbers? How many categories?

22

Can calibration procedure cross-index be defined that tracks equipment model numbers supported by a specific calibration procedure number?

23

How are calibration recall intervals accommodated? Can they be modified?

24

How are "parent" and "child" association of equipment supported?

25

How are special flags and alerts accommodated, i.e. Lockout / Tagout notice?

26

Can more than one technician document work against an open item?

27

How does the system validate calibration status of standards used?

28

How does the system manage the logging of environmental conditions during calibration actions, i.e. Humidity, Temperature, etc? Does this information automatically transfer into a certification report?

29

Can the system provide for the assignment of default calibration intervals to unique types of instruments (same models)?

Management Functions

- 1 Does the system have a user-friendly, menu-driven, report generator that is fully integrated with the database? If not, how are ad hoc reports generated?
- 2 What reports are delivered with your system? Please provide examples.
- 3 Can reports be generated and distributed to a screen, a file, a printer, an email address, and internet?
- 4 Can different types of mailing be defined? Can different followup actions be automated and defined? Please explain.
- 5 How does your system accommodate maintaining and tracking of individual training proficiency and records?
- 6 How are services tracked that do not apply to one item, i.e. engineering support, writing procedures, etc?
- 7 How is labor tracked?
- 8 Can charges and billing be captured and generated into client reports? Broken down by parts, labor, and vendor services?
- 9 Can special projects be established and tracked, e.g. capital builds?
- 10 How is customer information supported? Can equipment owners be defined for automated routing of scheduled reports via email?

Management Functions

11

How is an hourly charge rate accommodated? Can a default or "standard" hour duration be assigned to unique instruments (same model number)?

12

Does the system include features to manage work assignments, scheduling, prioritization, tracking, and reporting of Item Status, Tracking Status, etc?

13

Can the system generate current and future workload projections?

Database Administrator Functions

1

Do you recommend a dedicated systems administrator to support your system?

2

Can a Main Menu option be hidden from a user?

3

Can unused fields be removed from a screen?

4

How is data archived?

5

How are user defined fields accommodated?

Database Administrator Functions

6

Can selectable default data be defined for fields to eliminate accidental misspellings of equipment information during new add? What is the maximum number of pre-defined selectable data (List Boxes)?

7

How is the customer contact database managed? Can the system permit an unlimited number of contacts to be defined for each customer? How is this interfaced with recall reporting?

Logistical Functions

1

Will the system accommodate customer purchase orders?

2

Will the system accommodate spare parts inventories?

3

Will the system accommodate creation of invoices?

4

Explain the bar code support accommodated in your system?

5

Is Documenting Process Calibrators supported? How?

6

Describe the vendor management used by your system? Can the system track service provided by vendors, including quoted charges, actual charges, date sent to vendor, actual return date, etc? Can the system track vendor audit status?

7

Are mobile devices supported? How?

External Systems Interface

- 1** How does your system interface with Fluke MET/CAL software (Automated Calibration Software)?
- 2** How does your system interface with Northrop Grumman SureCal (Automated Calibration Software)?
- 3** Can your system interface with any Requisition and Procurement System?
- 4** Can your system interface with any Manufacturing Execution System?
- 5** What statistical software does your system support or interface with?
- 6** How does the system interface with Chart Recorders?
- 7** What other systems can you interface with?

Implementation

- 1** How do you handle conversion of legacy database data to your system?
- 2** What pre-implementation support do you offer?

Implementation

3

How are software and documentation provided?

4

Do you allow system software documentation, help notes, and all screens to be copied in whole or part for use in internal company procedures and work instructions?

5

What follow on support plans do you offer?

6

How do you support software utility programs required to link other systems, i.e. Fluke MET/CAL, Northrup Grumman SureCal, etc.?

7

Do you offer an annual Maintenance Agreement that provides all updates, upgrades, correction of defects, and phone service support?

Technical Requirements

1

Which programming language is used?

2

How will source code be made available? If the source code is not provided, will procedures be defined where source code access is provided in case of vendor disaster / liquidation / sale, etc?

3

Which hardware platform do you support?

4

On which databases do you run?

Technical Requirements

- 5 How is the link with Microsoft Office implemented?
- 6 How is the link to the internet organized? Does the system support direct queries from a website database engine for reporting equipment status to customers?
- 7 Which protocols do you support?
- 8 What data is held on the client?
- 9 Does the client run on the current Windows operating systems?
- 10 How does the user's workstation communicate with the main database?
- 11 Have you deployed your software system in a multi server configuration?
- 12 How is multi-language supported, e. g. by user, in reports, etc?
- 13 What operating system do you recommend for the Client Workstation?
- 14 Would you briefly explain the architecture of your database system?

Technical Requirements

15

How is access security being handled (local and remote)?

16

How is information security being handled, e.g. by module, screen, field?

17

How can the software be implemented in modules?

18

How can functionality be selected using parameters? To what extent, explain.

19

How can the software be customized?

20

Which development tool do we need?

21

How do we adjust screens and reports?

22

How do we transfer information between our logistics, financial and other systems?

23

How do we run batches?

24

Can a user work off-line? How?

Technical Requirements

25

If changes are made to data, how are these changes distributed to the off-line users?

26

How is a selection made on the information to be down-/uploaded?

27

How is information transferred through the internet?

28

How is workflow incorporated?

29

To which mail systems do you interface?

30

How can the address list in a mail system be used?

31

How is online help available?

32

How can we adjust / create online help?

33

How can help text be exported to MS Word?

34

Are wizards available? For what tasks?

Technical Requirements

35

What features are available to make the system user friendly (e.g. toolbars, short cut keys, scripts, etc.)?

36

How many updates were released in the last 12 months?

37

When is the next release expected?

38

What will be in the next release?

39

Can your system run on one server?

40

Provide a brief description of the portability and scalability of your system?

41

Does the system have an API?

Vendor Requirements

1

When was your company founded?

2

Where is the headquarters?

Vendor Requirements

3

How is your company organized?

4

Where are you located?

5

Who and where are your distributors?

6

How is implementation support organized?

7

How do you support implementations?

8

How is operational support organized?

9

Which customers do you have in the line of business medical manufacturer?

10

Which customers do you have in the line of business pharmaceuticals?

11

Which customers do you have in the line of business biotech?

12

What is the primary line of business you serve?

13

How many installations do you have worldwide, in North America, Asia, Europe? World wide: North America: Asia: Europe:

Vendor Requirements

14

How many employees do you have worldwide, in North America, Asia, Europe? World wide: North America: Asia: Europe:

15

Is the company publicly held? If yes, which stock exchange and what has been the performance?

Price

1

Please explain how the price is built up with different options.

2

How do you count licenses?

3

Is there an additional charge for the development tool? How is this organized?

4

Is source code included in the price? If not, what will be the additional charge and how is this organized?

5

Are databases, standard interfaces included in your price? How?

6

According to your experience, what are the costs for implementing?

Quality

1

How many days of training can be expected? Break out into areas.

2

What training documentation is provided?

3

Do you provide training to users (technicians), clients, administrators, and managers? How is this performed?

4

Can you accommodate multi-language training and documentation, i.e. French, German, Spanish?