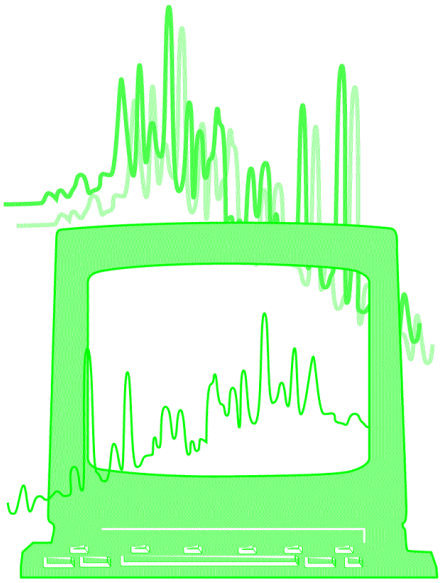

Chromatography Data Systems II: Specifying, Evaluating and Selecting a System

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In the first part of this series (1) we covered the overview functions of a chromatography data system (CDS); we looked at the workflow associated with a system and the system development life cycle based on the ISO 'V' model. In this article, we'll concentrate on looking at the first phase of the life cycle: the specification, evaluation and selection of a new CDS.

This article brings together a number of elements of the workflow and the functions of the system as you use them in your laboratory. The emphasized text is important. Although most CDS have similar workflows, the details will differ and so will the operations of most laboratories. The key issue is to match your current or planned workflow with a CDS that has a similar one. Alternatively, if you don't like the way you work currently, redesign your process and automate the new one with a CDS. The choice is yours.

Seduced by Technology

Never happens to you does it? It's always somebody else who goes to the equipment show and comes back singing the praises of vendor X's CDS. Let's go through a list of some advantages gained in first impressions:

- better user interface?
- superior A/D units?
- easier calculations?
- simpler reporting?
- all of the above (and more)?

(The alternative scenario is that the sales-person bought me a good meal, which doesn't look as good in print as the list above.)

First impressions, plus a rapid decision to buy based on a show visit, will save time in the initial stages for a CDS, but the users will be paying for a system selected by naive purchasers for the rest of the life of the system; thus modifying the old saying "Buy in haste, repent at leisure." Many adverse comments about a CDS in a specific laboratory arise because the system was never properly evaluated in the first place and the limitations of the system come as a (nasty?/welcome?) surprise to all in the project (users and vendor alike). Thus you may never know what the system is capable of until it's installed.

Is this the right way to approach the specification, evaluation and selection of a CDS? Of course not! However, this is a prime example of being seduced by technology. We all know of examples where this has happened, don't we? But, of course, this never happens in your organization.

What we have to concentrate on is the selection of a system based on business need and what the whole user base requires. I appreciate that this may be a novel concept to many of you, but to deliver a CDS that does what the users and the business need should be the overall aim. To do this effectively will take time and effort, but this will be repaid many times over when the correctly selected system works effectively and as required. Contrast this with a system for which you need to find a work around to obtain the desired input to or output from the system.

OK sermon over, let's look at the process we should go through to specify, evaluate and select a CDS. This is shown in Figures 1–3.

- Define what you want in a user requirements specification (URS).
- Prioritize your requirements into those that are mandatory (must have) or desirable (nice to have).
- The URS and the prioritized requirements define the selection criteria and are also the basis of your selection tests.
- Write the request for proposal (RFP) or invitation to tender (ITT) document to send to vendors.
- Select potential vendors and send them the RFP.
- Evaluate RFP responses and select systems for evaluation.
- Apply the tests to evaluate systems and assess the results.
- Visit or talk to existing users of a specific vendor's system.
- Make a decision and select the system.

The sequence above is an expansion of the first stage of the life cycle we looked at in the first article.

These are some of the approaches you can use. You can adapt any of these, extending some sections or omitting others. This is simply guidance based on my experience. Regardless of your approach, you'll have to go through a life cycle of some description to ensure that what you are purchasing meets the business needs of the organization and the chromatography laboratory community. The life cycle is your map through the maze and should be used to guide you. What I am going to describe here is basic common sense. Unfortunately, common sense and the specification, evaluation and selection of chromatography data systems do not appear to be good bedfellows or even considered in the same breath.

Write the User Requirements Specification

Why write down your requirements? Best practice in selecting a computerized system for the chromatography laboratory, or anywhere else for that matter, is to define your requirements before starting the selection process. There are a number of ways to define your requirements but all must be written down on paper in the end so that you have a fixed point of reference for the remainder of the process. Oh not more paper, I hear you say? Afraid so, but this will help you get the right system for your laboratory.

An alternative argument for not writing your requirements down on paper is "all chromatography data systems are the same." In part "yes," because the high-level functions they perform are the same: acquire data, process data and report results. However, the way that they go about it will differ, sometimes markedly so.

Consider the function of your laboratory.

- Forensic or environmental laboratories will have requirements for a chain of custody that a general chemical laboratory would not need.
- Very high throughput for a combinatorial chemistry analysis laboratory will place very stringent requirements on the capacity of the system, including the ability to define sequence files for the analysis of multiple 96- or 384-well plates, but such a laboratory tends to have relatively few analytical methods.
- A quality-control laboratory may have a lower number of samples for assay per analytical run but tends to have a large range of analytical methods.
- Post-analysis calculations tend to be specific to individual laboratories and these should be specified in your URS.

It is for these reasons that all chromatography data systems are the same — except, of course, for the differences. Just as all laboratories are the same — again except for the differences.

Writing the first draft: The overall process of writing the URS is shown in Figure 1. Inputs to the first draft of the URS could be the following:

- Your current or proposed ways of working, which can be defined in a process flow or in existing written procedures but only if they are accurate and have sufficient detail.
- Corporate requirements should be included here: must the operating system be of a specific type? Currently there is a move towards Windows NT in many organizations as part of developing common operating systems or environments. A prime requirement may therefore be that the final selected CDS runs on a specific operating system. Similarly, if a database is required, should it conform to specific corporate standards or can any database be used? There may be other requirements involving an IT hardware platform that need a specific manufacturer for reasons of corporate policy.
- Design constraints are those requirements that may limit your choice of system. An example of such a design constraint is the need to control chromatographs from the data system. This requirement must be mentioned up front as it will limit the number of vendors that will be able to respond to this requirement. Instrument control of another vendor's equipment by a data system is an increasingly common requirement that is being pushed by user pressure on vendors. Another design constraint would be the stated need to have a data system with a database. This again will limit the number of vendors able to respond to your tender.

These are the inputs to the URS. Often you will have these available in written form and these will reduce the time needed to write the URS. However, many laboratories do not consider using these inputs to define their requirements, which will make the process longer or will mean that the step is not performed and this is the start of the slippery slope to the selection of the wrong system.

Structuring the requirements: There are a number of options to structuring the requirements specification, such as looking

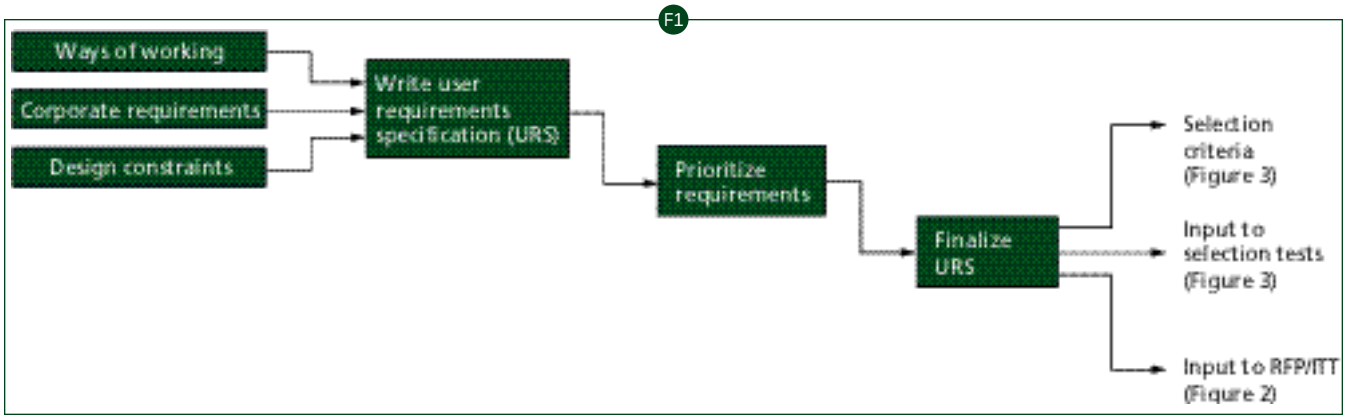

Figure 1: Process for writing the user requirements specification. Note: Feedback loops in the process, e.g., review and revise document, have been omitted for clarity.

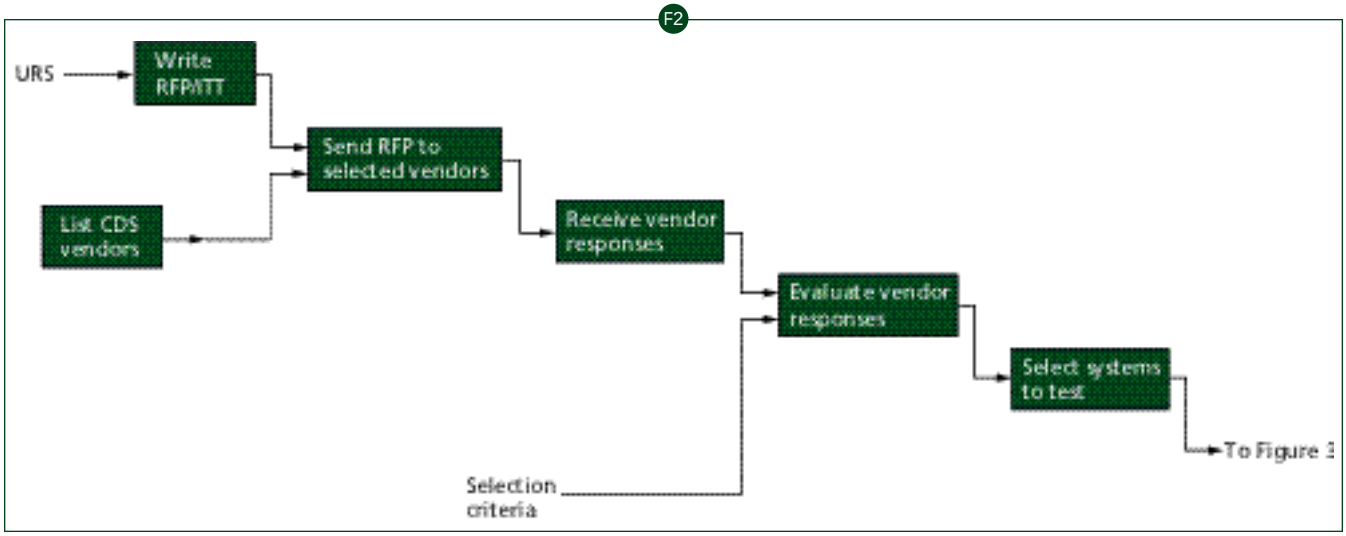

Figure 2: Process for selecting systems to test.

at the workflow of your laboratory typified using the diagram from the first article in this series (1) or looking at the way you want the new chromatography system to operate. In the latter situation, you have a good starting point if you use an existing CDS. You can use the strengths and weaknesses of your current system to formulate the requirements for your new one.

Regardless of the approach, you'll need to collect and revise your requirements into a document. This has a variety of names:

- user requirements specification
- system requirements specification (SRS)
- request for proposal
- invitation to tender.

Consider the list above as two pairs of documents: URS and SRS, and RFP and ITT.

The URS and SRS pairing are names for a document intended for defining the requirements of the system from the users, information technology (IT) and corporate perspectives. The RFP and ITT documents take the first document as a basis and then add additional information to send to any prospective vendor to enable them to bid for the contract to supply the CDS (make a proposal or submit a tender). In this section we'll look at defining the requirements for the CDS.

The easiest way to structure a URS document is around the workflow for the system. Here the main sections are comprised from the major process steps, which include

- method definition
- instrument control
- defining an analytical run
- data acquisition
- data processing
- calibration
- reporting.

Each of these functions will need to be broken down into more detail with information of capacities used by your laboratory. Let's look at two examples of this way of defining requirements in a little more detail: we'll look at the sequence file (setting up the analytical run) and calibration.

Defining sequence-file requirements: The sequence file, as we saw in the last article, is the order that the samples are to be injected into the chromatograph. Some of the user requirements can be listed here:

- average and maximum numbers of samples to be injected in a batch
- number of replicate injections (from single to triplicate)
- types of sample to be injected: unknown sample, standard, blank, quality control, etc.
- positioning of standards and unknowns (e.g., run sequence) (2)
- linkage with any calculations with data input such as weights, dilutions, etc.
- custom calculations that will be performed on unknown samples
- single or multiple methods per sequence?
- ability to modify a sequence file during a run (e.g., addition or removal of samples).

You can start to appreciate the differences that could occur between laboratories over something as relatively simple as the sequence file.

Defining calibration method requirements: Calibration is a weak area with most chromatography data systems. This is because chromatographers use many ways to work out their results. Often these methods are basic and lack statistical rigour, as the understanding of many chromatographers, where calibration is concerned, is poor. For instance, several data systems have a number of calibration functions such as cubic, quadratic and log-log fits. In my opinion, there is little justification for using some of these models with conventional chromatography (e.g., liquid chromatography with ultraviolet detection) that follows the Beer-Lambert Law.

In one laboratory you might want to use bracketed standards at one fixed concentration or amount (this may be a requirement that is linked with the sequence-file requirements). Within another, you may require measurement of an analyte over a range of amounts or concentrations. Equally so, the number of analytes to be measured in a method may vary from one in a quality-control laboratory to over 100 in a petrochemical analysis.

The data system may not be able to cope with one or both ways of working. This is not a problem that is confined to inexpensive integrators and which goes away if you purchase a more expensive system. Poor calibration is a problem that affects all data systems regardless of size and price.

Number of calibration points: How do you work? You'll need a system that can cope with your needs now and those anticipated in the future. If you work over a wide concentration range, the system may need to cope with up to 10 different levels with each up to triplicate (i.e., a total of at least 30 calibration points). The standard samples could be positioned anywhere within the sequence file or randomly dispersed as we discussed in a recent "Questions of Quality" column (2).

Multiple analyte calibration may need to be incorporated within this framework, if that is how you work. Often standards are run as either single or mixed components. If run as the latter, the system should be

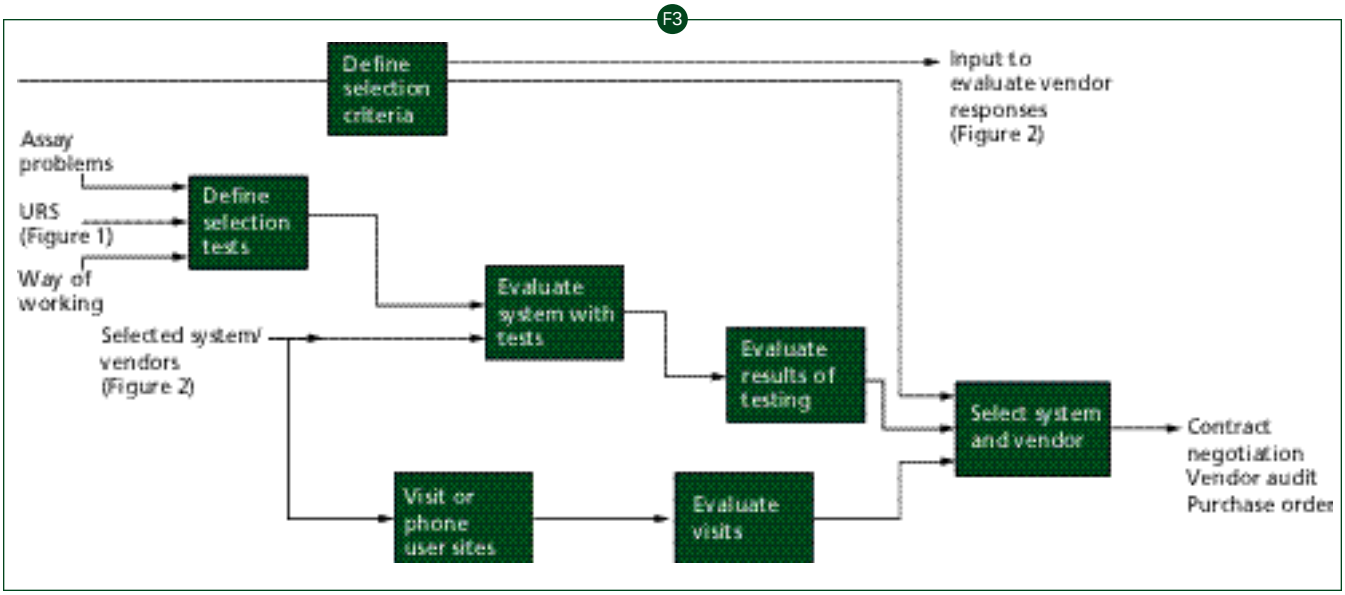

Figure 3: Testing and final system selection.

able to incorporate them into the standard curve at the appropriate concentration. The incorporation of a blank or zero standard into the calibration curve should be an option. Displaying a calibration line: Each plot of a calibration curve should be identified uniquely for that calibration line and the analyte to be determined. The display and plotting of the mean of replicate standards is not sufficient, in my view, as it would obscure data trends and outliers that you need to see. The calibration curve should show all calibrating standards run in any particular assay. It should then be possible for the user to remove selected standards from the curve (e.g., by highlighting the point) if they are not required, according to a defined procedure and with established scientific criteria, with annotations of who made the change, when and the reason for the change. The calibration curve would then be recalculated and displayed. If satisfactory, the curve would then be printed. It is important to note which standards have been removed and the reason for their removal either as a 'footnote' or as a different symbol on a curve.

In assays containing more than one analyte it will be necessary to interpret all the calibration graphs before the calculation of results. Again, this is an area that tends to be poor on many data systems as often only one calibration model may be possible for all analytes measured, regardless of the model the user wants to select.

Ideally, a user would want to compare results of different standard curves or response factors used for the determination of the same analyte to give the analyst an idea of the variability of an assay over time. Database or directory? At an early stage in your data system project you may want to consider how you want to structure and organize your data files. The two options that you have are either directories or a database. The overview is shown in Figures 4 and 5. Let's look in more detail.

- Directory: This approach uses the operating system to define directories to store data files and link them with the data channels from specific chromatographs as shown in Figure 4. To operate effectively this requires specific knowledge of the operating system. The system manager

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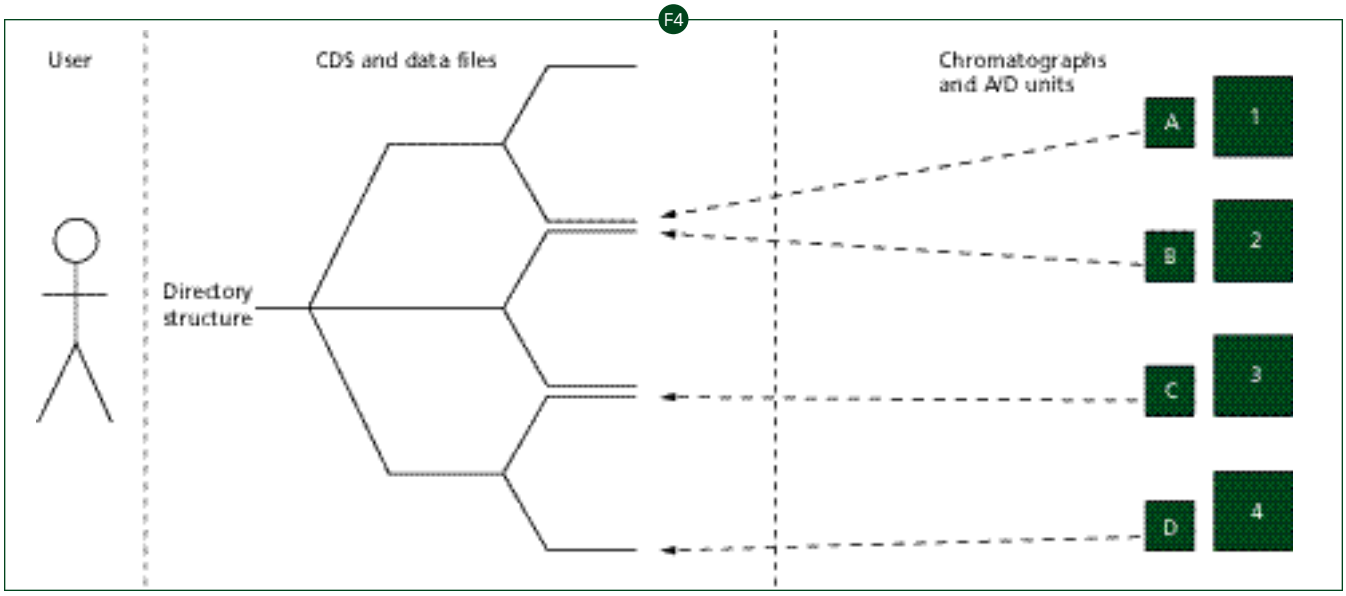

Figure 4: Directory structure: linking data acquisition channels to individual sub-directories.

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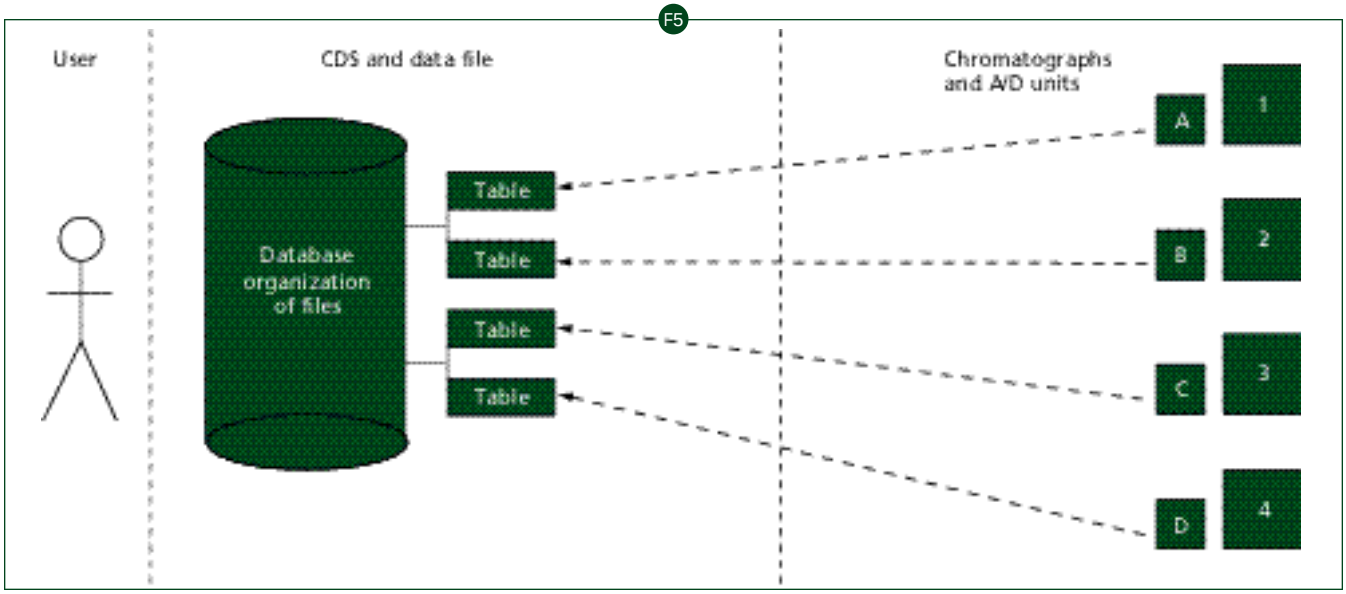

Figure 5: Database organization: linking data acquisition channels to database tables.

usually performs this operation, as a knowledge of the operating system is needed, together with a strategy to ensure that the data files are organized and managed successfully. This is especially so when a chromatographer wants to archive or retrieve the files from analyses; thus this strategy may also be linked with naming conventions for data file names.

- Database: The use of a database takes the hard work out of defining, naming and organizing the data files and associated data. The security surrounding this function needs to be handled carefully as you don't want every user being able to define and delete data file organization in just the same way as the directories above. What will usually happen is that the software will define a table in the database with a default size (table space). The database table organizes the data files that are hidden from the user. A problem occurs if you acquire more data than the default table space because you'll have to increase the size. Increasing the default table space to avoid or defer this process will waste disk storage.

In my view, the use of databases to manage and organize chromatography data is still being developed. It hides much of the work from the user but it also adds an extra level of complexity that a laboratory or organization will need a knowledge of to manage the database.

However, the real uses of a database in a CDS have yet to be seen. Imagine you have a routine method and one day you see a peak that you have not noticed before. Questions may arise such as is this transient or is this a regular feature that has not been observed before? The use of pattern-recognition software to compare data files of the same analysis to see the extent of the problem will be better automated by using the database organization. These features will be some way off unless requested more forcefully by users. Again, if there is no commercial interest there will be no commercial product.

Electronic signatures and records: These have been driven by the requirements of the US Food and Drug Administration in the regulation of the pharmaceutical industry. As a result, many vendors are offering electronic signature functionality in their products to maintain or increase sales to pharmaceutical companies. Many of you will eagerly read this and be immediately disappointed as this will be the subject of a "Questions of Quality" column and not covered in this series.

However, I would like to make the following brief points concerning electronic records and signatures.

- The regulations only define systems and not applications. Therefore, you will have to consider the IT infrastructure as part of the system. To many laboratories, this is a black box operated by "them." I would advise you to ignore this at your peril, as IT departments will be in the regulatory front line in the next few years as they manage more of an organization's electronic records and Good Manufacturing Practice/Good Laboratory Practice (GMP/GLP) critical systems.
- Most CDS would be defined as a closed and not open system as the data they produce are under their direct control.
- Any move to electronic records requires that the data system has a fully functioning audit trail to ensure that the data generated are trustworthy.
- A move to electronic records will require a definition of raw data (original observations taken to be the raw data files) together with other files such as the associated method, integration file and injection sequence to enable the work to be reassembled. The definition of chromatographic raw data was discussed in an earlier "Questions of Quality" column (3).

In any event, you'll need to define the requirements for electronic signatures and records in your URS.

Review and revise the URS: Not shown in Figure 1 are the feedback loops that occur during the review of the drafts of the URS and the revision process. These are very important as the quality of the final document is improved with this process. Ignore this stage at your peril and do not rush!

Ideally, you should have a group of reviewers who were not involved with drafting the document so that they can give good feedback to the document. Feedback and constructive comment will challenge the statements written in the URS and enhance it further. The purpose of the review is to eliminate any ambiguous statements, pick up any duplication and identify gaps that are not covered adequately or are missing. For more details about the URS, please read an article in Scientific Data Management (4).

Prioritize your requirements: Let's be honest here, what you'll define in your URS may never be achievable. Therefore, the best approach is to prioritize your requirements into at least two areas:

- mandatory (must have functions)
- desirable (nice to have functions, but the system can operate without them if not available).

You can grade the functions further, but in my opinion it can make the selection process a little more difficult.

The process for selecting can be done in a variety of ways, as long as the users are involved along the line. This is vital for acceptance of the selected system and it is important to carry the user base with the laboratory management. Too many laboratory systems have wasted money by ignoring this part of the process.

Finalize the URS: After the first draft of the URS has been written, it will be reviewed and modified as described above. Again this will involve the users who will comment on the requirements so that the authors can update the document. When agreed, the final document should be authorized by the laboratory manager.

T1

Table 1: Matrix of Requirements versus Vendor Proposals.

Sequence File Requirement	M/O*	Vendor 1	Vendor 2	Vendor 3
Link sequence file to a single method	M	OK	OK	OK
Link sequence file to multiple methods	M	OK	OK	OK
Laboratory i.d.: Input 25 characters	M	OK	Only 20 chars max.	OK
Sample identification free text field 25 characters	O	OK	Only 20 chars max.	OK
Sample dilution calculation from 1:1 to 1:10	O	OK	No reply to question	OK
Sample weight input in mg. Range 1–10 g	M	OK	OK	OK
Injection volume in range 10–200 µL	M	OK	Max. 100 µL volume	OK

* Prioritization of function: M = mandatory requirement, O = optional requirement
Note: for reasons of simplicity, no weighting of requirements has been included in this table.

Once final, should the document remain unchanged and cast in stone? No, you may revisit your requirements after seeing some systems or visiting user sites. However, the URS must be a document under change control. Updates, modifications and deletions of requirements cannot be made on a whim of an individual. Changes should be made under a controlled process and a new version of the URS issued that contains a change history.

The URS is now used in three areas:

- definition of the selection criteria (Figure 3)
- input into the request for proposal or invitation to tender document (Figure 2)
- input into the selection tests on evaluation (Figure 3).

We'll look at each use in turn.

Selection Criteria

Although the generation of the selection criteria is presented in Figure 3, the selection criteria are used in two places within the overall selection process:

- initial paper selection of vendor proposals
- definition of the selection tests for the shortlisted systems.

We'll look at the definition of the selection criteria in more detail below and how they are used in the process later in this article.

Definition of selection criteria: Once the URS is completed, the final requirements together with their prioritization are used to define the selection criteria. In essence, these are the minimum requirements that any CDS must attain for it to pass to the next stage of the evaluation and selection process. The selection criteria are mainly the mandatory requirements from the URS. You'll normally create a separate document from the URS to define these criteria.

Weighting schemes: There are further enhancements to help make selection accurate (or more complex depending on your viewpoint). Each mandatory requirement is given a weighting value usually between 1 and 5 or 1 and 10, depending how many fingers or hands you want to use! The greater the weighting value used, the more important the function to the overall selection and, therefore, the greater the emphasis in the selection process. Therefore, a mandatory requirement with a weighting of 5 is more important than one with a weighting of 2, but less important than a requirement with a weighting of 10. The weighting values can be summed across all the requirements to give a total score for the selection criteria as a whole.

When a requirement is evaluated, either from a tender or proposal or from an actual test, a score will be given. This will be multiplied by the weighting value to give a value for that vendor's system against the requirement. The individual results from a vendor proposal or evaluation test can also be summed to give an overall score for a system. Comparison with the maximum attainable score from the selection criteria as a percentage will be the fit of the system to your requirements — in theory.

Note that the process is pseudo-objective or semi-subjective. It relies on a group of users and IT professionals drawing up the criteria and defining the weightings. So far so good. It then relies upon the interpretation of a vendor proposal or tender document: written by a vendor to try to meet your requirements; you have to understand the nuances of the response and mark it against your requirement. The paper evaluation is probably the more difficult compared with the on-site evaluation during which you can be far more objective. Still one person's definition of user-friendly will be different from another's…

Identify Vendors and Preliminary Selection

We have looked at the preparation of the user requirements as outlined in Figure 1. The next steps, using the URS as input, are outlined in Figure 2 and deal with the selection of the vendor and the system.

Write request for proposal: This stage of the process is relatively simple: it takes the URS and puts a framework around it that permits a vendor to submit a paper proposal or tender (hence the request for proposal or invitation to tender). Typical in the request for proposal are items such as

- deadline for the proposal to be submitted to you
- format of the response: paper and/or electronic?
- format of the document response: this is important as you'll need all vendor documents to be structured in the same way. If you don't believe me, ignore this step and try to work your way through six documents written in different ways.
- expectations of the response format: how much do you want a vendor to write? What proportion of technical information to marketing verbiage would you like? Manage the expectations on these fronts by defining the format of the response and it will help you reduce some of the work in the evaluation stage.
- how many copies of the document do you want? It may be better to have a single copy from the vendor with a duplicate in hard copy that can be circulated to the evaluation team. At the very least, it should save a few trees, providing the recipients don't print out their own copies.

List CDS vendors: In parallel with writing the RFP, you'll need to know which vendors to send the document to. Some vendors are well known but you may also want to consider local or emerging suppliers as well. Search trade directories or use the August issue of LC•GC International, which lists CDS suppliers.

Determine which vendors to send the RFP to: this may be based on personal experience or prejudice (which amounts to the same thing), and the design constraints (operating system, database, instrument control, etc.). For reasons of practicality, I would suggest not sending the RFP to every data system vendor listed in a directory, as you will end up drowning in paper.

Send RFP to selected vendors: Once you have shortlisted the vendors, you'll send them a copy of the URS and the tender details in the RFP. If you want a short turnaround, phone the vendors concerned in advance and let them know the document will be coming and that you want a rapid response. Don't expect a turnaround within a few days but at least two or more weeks, especially during holiday periods.

Receive and evaluate vendor responses: Responses or tenders should be received back from the vendors within your deadlines. At the end of the period you'll have several documents and the corresponding electronic files. What are you going to do with these documents? You'll evaluate them against the URS requirements and your selection criteria based on them. The selection criteria are compared with the vendor responses to see how well they match.

You'll evaluate the chromatographic needs versus the vendor's statements to see how well they match, and experienced chromatographers should be able to undertake this without too much training. In addition, you'll need to evaluate the technical aspects of the IT architecture: the database (if used), the client-server set-up and how data are buffered over the network. Here you may need input from the IT department in your organization. This input will be very forthcoming if they have been informed or involved in the whole project rather than having had several large documents dumped on their desk with little or no warning.

One of the end products of a paper selection process will be a list of prioritized requirements with each vendor's tender response stating whether they meet the requirement fully or partly as shown in Table 1. The table shows the sequence-file requirements for a laboratory, together with

the prioritization in the next column. Then, three proposals from vendors are listed in the next three columns, together with an evaluation of each against the requirements. As you can see from the table, vendors 1 and 3 appear to meet the requirements acceptably; however, vendor 2 does have some limitations in both the length of data inputs for text comments and laboratory identities. Furthermore, the maximum injection volume appears to be limited to 100 µL. In this hypothetical example you can begin to see that vendor 2 is starting to fall behind vendors 1 and 3. If this is consistent throughout the proposal, it will be an easy decision to reject the system. It may be more difficult to distinguish between vendors 1 and 3.

Select systems to test: Based on the overall responses to your RFP you will select 1–3 systems for testing. You can test in-house or at a vendor site. From a personal view, I think it best to test in-house under your conditions. This also allows other people to see possible systems and to comment on them.

Define Tests, Evaluate and Select the System

Figure 3 outlines the final stage in the overall process, definition of the selection criteria (already covered above), defining the tests to apply, testing selected systems, visiting users and making the final system selection. Easy really!

Define selection tests: Wealth Warning! Please don't do this in your laboratory: bring a shortlisted system into your laboratory, play about with it and select the system based on a few subjective comments.

Such an approach can seriously damage your organization's wealth.

Here's a novel idea — define some tests and apply them to each system to be evaluated. Better still, ensure that they are based on your mandatory requirements.

Taking the workflow of your laboratory, URS and the selection criteria, you'll be able to put together a series of tests that can be used to evaluate a system. Consider what methods you have at the moment, you'll need methods that typify how you work:

- single or multiple analyte measurement?
- average and maximum numbers of samples to be injected
- replicate injections as you would use under normal circumstances
- test all calibration methods you'll want to work with
- define the reporting formats you'll want from the system
- what common analytical problems or analyses have you had in the past? Can you devise tests based around these?
- IT evaluation of the architecture.

This list is not exhaustive but will give you an idea of what is required. Again base the tests around the selection criteria. If you are smart, you can use the tests developed here as the basis for your user acceptance tests or qualification tests when the selected system is installed.

In addition, don't forget some of the subjective issues surrounding the system such as ease of use and how user-friendly the system is. This latter point is open to some considerable debate because what is user-friendly to one user is not to another. Here you should take the opportunity to show all the user base the system while it is in on the evaluation and ask for their feedback.

Test systems and evaluate results: This stage is simply the application of the tests and checking the reports and other output against the selection criteria. Normally the output from this stage would be a report of some description detailing the systems tested and the preferred selection based on these results.

To be successful, you'll need to ensure that you have sufficient resources available to undertake this work. Ideally, the same people should be used in all evaluations to be consistent. This needs to be planned up front and agreed with laboratory management to ensure that the evaluations go well and that you do not short cut this part of the life cycle.

Visit user sites: At the same time you are evaluating shortlisted systems, you can either phone existing users of the system or if permission is given, visit the sites. This will give you a track record of how a system is used in practice and how the vendor supports existing customers. Ideally, you should select a user that works in the same industry, supports the same work as you and has at least a similar size installation as you are planning. Again, plan what you want from the contact and keep a record of the visits or phone calls, which will be useful when you make the final system selection.

Select System and Vendor

The final task for system selection will be to look at the

- vendor's proposal (a rereading is recommended after an evaluation to see how close to reality the tender is)
- results of the evaluation tests and how close they were to your requirements
- fit with the organization's IT policies and practices
- price and terms to ensure that they are acceptable for the purchasing organization.

Make the decision based on objective evidence as much as possible. Before you place the purchase order, you'll need to consider whether a vendor audit is worthwhile.

System Quality — The Role of the Vendor Audit

Once the system has been selected, but before the contract has been negotiated, you should consider a vendor audit. The purpose of this is to check that the design, build, testing and release is under control and is a managed process. The last thing you want to see is a vendor producing monthly updates of software as this would suggest that there is no control in place.

A vendor audit can be done either remotely or on-site. If the system you are purchasing is very critical an on-site audit is best. I'll not discuss this further as this was the subject of a "Questions of Quality" column (5) as well as the papers by Segalstad (6, 7) and McDowall (8, 9), which give more information on the subject.

In the next article in the series we'll look at validation of a CDS and the documented evidence you'll need for this.

References

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