

# Chromatography

## Specialty Chromatography Detectors: Make or Buy?

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Liquid Chromatography of any kind - HPLC, UHPLC, GPC/SEC, Ion Chromatography or FPLC, is based upon the specific characteristics of the utilised separation column to provide a suitable environment for a particular application or investigation. As such, creating an optimised separation is often considered to be the core of an individual liquid chromatography system. Separation alone, however, does not supply answers, it just creates the correct preconditions whereby chromatography detectors are able to reveal the 'secrets' of your sample.

Chromatography detectors have undergone significant development over the past 40 years, from simple single fixed wavelength UV detectors to now the widespread use of specialty detectors designed for specific tasks or problems. Chromatography detectors of just 5-10 years ago look almost primitive in their capabilities compared to today's new generation of specialty chromatography detector technology. Significant advances in performance have been coupled with major advances in usability and reliability.

When a liquid chromatography manufacturer evaluates whether to develop in-house (make) or partner with an external company (buy) a new, specialty detector - performance, whilst important is not the only factor to be considered. The same make or buy evaluation also applies to financial considerations, they are indeed important, but not decisive alone. In most circumstances, the decision about whether a new specialty chromatography detector should be developed in-house or sourced under an OEM arrangement from an external partner, is led by a relatively complex decision matrix which considers aspects of three different key factors (know-how, resources, time). Each of these factors, in a new development, need to be carefully considered and assigned a decision weighting according to their individual contribution to the desired resultant product, according to the company general policy, particular situation, market situation and outlook.

It is important to note, that it is nearly impossible to generate a typical development decision table, as such a table is intrinsically specific to the particular situation of the organisation in the process of deciding how to develop their desired new specialty chromatography detector. However, each development project does have some common decision process that can be considered and looking at these can be helpful as a starting point.

As previously mentioned, the three fundamental factors influencing decision making are:

- A) Know-How
- B) Resources
- C) Time

### The Necessary Know-How for the Task

The 'Know-How' category is probably the most challenging of the three, as it requires prior deep knowledge of the desired product to lead to a solid evaluation. First, it is necessary to assess what type of Know-How is required; is new research needed or is the project more of an engineering development? This is typically the first point to be made clear. Engineering must be evaluated under different branches of the discipline - mechanical, electronic and firmware/software engineering. Table 1 summarises how to define internal availability of the know-how necessary to complete the development.

#### Know-How Table

Select parameters relevant to the internally available Know-How aspect for the project. Answer with Yes or No to each question and determine the importance of each parameter by assigning individual weights to them. A Yes with a high weight (10) means the parameter is very important and possible in-house. A No with a high weight (10) means the parameter is very important and difficult to achieve in-house.

Table 1. How to define internal availability of the necessary know-how to complete the project.

	Yes / No	Weight (1-10)	Comments
Is research necessary for the project?	No	1	
<b>Is prior experience available?</b>	<b>No</b>	<b>7</b>	<b>Important factor</b>
Is Mechanical Engineering necessary?	Yes	2	
Is Electronic Engineering necessary?	Yes	2	
Is Software Programming necessary?	Yes	5	

### Final Table result

While no new research is required, prior experience of the technology is considered the most important know-how factor for this project. This prior experience is not available in-house. In this scenario a **NO** will be reported to the final table.

## The Resources to Complete the Task

Having considered whether you have the necessary know how to develop the new detector, the next step is to determine whether sufficient in-house resources are available to complete the project. Resources is a very generalised term that covers different aspects. This category includes manpower, the finance to cover salaries for the term of the project, production of test equipment, prototypes, purchase of necessary tools and so on. It also includes capability of manufacturing the product in the required quantities once the development process is completed.

### Internal Resources

Select parameters relevant to availability of internal resources for the project. Answer with Yes or No to each question and determine the importance of each parameter by assigning individual weights to them. A Yes with a high weight (10) means the parameter is very important and possible in-house. A No with a high weight (10) means the parameter is very important and difficult to achieve in-house.

Table 2. How to define internal availability of the necessary internal resources to complete the project.

	Yes / No	Weight (1-10)	Comment
Is required tooling already available?	Yes	2	
<b>Are any of the required development assets (Hardware/ Software) or test equipment already available in-house?</b>	<b>No</b>	<b>10</b>	<b>Important factor</b>
<b>s it possible, to undertake the project development using a platform already available in-house?</b>	<b>No</b>	<b>10</b>	<b>Important factor</b>
Is sufficient manpower readily available for the project?	Yes	5	
Does facility for prototyping new products exist in-house?	No	2	
Can the final product be manufactured in the required quantities in-house?	Yes	3	

### Final Table result

The available internal resources do not cover several important aspects of the project, investment would be necessary first, to close the gap in terms of assets and prototyping. In this scenario a **NO** will be reported to the final table.

## Time Required to Complete the Development

Time is always the enemy when it comes to innovation. On one hand, creation of a new product needs time, on the other hand, innovation itself is a function of time. For example, what is a great new product today might be 'common' or outdated one year later. Development time is typically dictated by the size of the market opportunity, competitive forces and is of course influenced by current activities of the company. For example, if the introduction of a complete, new chromatography system is planned that requires a new specialty detector X, then time gains a whole new meaning. Any delay in the development of X would affect a major goal of the company.

### Time Consideration Table

Select parameters relevant to the time aspect of the project. Answer with yes or no to each question and determine the importance of each parameter by assigning individual weights to them. A Yes with a high weight (10) means the parameter is very important and possible in-house. A No with a high weight (10) means the parameter cannot be difficult to achieve in-house.

Table 3. How to define internal availability of the necessary time to complete the project.

	Yes/No	Weight (1-10)	Comments
<b>Is time taken to complete project critical</b>	<b>Yes</b>	<b>3</b>	<b>Critical factor</b>
<b>Is time taken to complete project critical for related products?</b>	<b>Yes</b>	<b>3</b>	<b>Critical factor</b>

### Final Table result

Time is a very critical factor for this project as it influences other related projects too. Successful completion of the project must be assured within a set time, delays will lead to serious loss of competitive advantage. In this scenario a **YES** will be reported to the final table.

## Putting it all together

The information collected in the three tables described above, needs now to be combined into a single much simpler internal development decision table.

Table 4. Internal Development Decision Table.

Transfer the results obtained from the three key factor tables above to evaluate the possibility of fulfilment with internal resources only.

Topic	Is an Internal product development the best choice?	Critical factors behind this analysis
Know-How	No	Little of the prior experience is possessed in-house.
Internal Resources	No	Almost no hardware, software or testing assets relevant to the project exist in-house. No existing platforms are available for modification.

Time to completion	Yes	<u>Time is the most critical factor</u> for this project. Unfortunately, no unallocated internal resource is freely available.
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### Final Result

Overall undertaking this product development using internal resources is not a good strategy. An external partner is required. The focus must be on a partner with prior experience with the product technology in question and with sufficient resources to guarantee competition of the project within the required time.

## A Product Development Case Study

To illustrate the above process, we can refer to a 'real-life' case study. For confidentiality reasons, I will not disclose the client or the product. However, I will demonstrate how this one particular client, followed the path described above to reach a conclusion and decision about how to develop their new product of interest.

The subject of this case study was a small instrumentation company focused on the application of established analytical technologies to new fields and applications. In addition to having a strong knowledge of the theoretical aspects of technology to be developed, the client also employed numbers of engineers whose main task was the translation of technology from a known application field to the new application of interest.

The field and application this client targeted, required two new chromatographic concentration detectors, one capable of the determination of total sample mass and a second capable of selectively detecting two different compounds within the sample. The target application also required that the detectors be able to operate at relatively high flow rates and concentration levels, not typical for most analytical applications.

Although internal expertise about technologies, applications and software integration of different devices were available in plenty, the client recognised that time to complete the project and availability of resources were the critical factors. As a result, the client decided that partnering with an established external developer of chromatography detectors should be the preferred solution.

Testa Analytical Solutions was then asked to propose solutions for both detector developments. A careful evaluation of requirements within the three categories mentioned above, clearly showed that Testa Analytical Solution was a good partner for the task. The client appreciated that we were able to modify two chromatographic detectors already available in our technology portfolio and optimise both to the target application in a short timeframe, thus fulfilling their key development decision criteria.

## Summary

A clear path to deciding whether to make or buy a new chromatography specialty detector, is key for commercial success. This is true for both, the organisation desiring to introduce a new instrument and the potential OEM supply partner. Decision tables are known for being extremely helpful in a number of business decisions, OEM partnerships are a great example of their effective use. By using decision tables - organisations are able to make an evidence-based decision as to whether sufficient knowledge, resources and time are available internally for their development task. In addition, decision tables assist potential OEM developers to identify the real needs of the client thus making sure that the most appropriate package of actions is proposed. The illustrated case study, although with very limited information due to the confidential nature of all OEM business relations, led to a mutually beneficial, long-term business partnership. Using this process for decision making has proven to be an invaluable tool to identify and provide a solution to analytical instrument companies faced with choosing make or buy product development scenarios to enter a new market, increase competitive edge or solve a challenging application.

## About the author

Carlo Dessy is Managing Director of Testa Analytical Solutions eK, a respected OEM developer of liquid chromatographic instruments, related detectors and software.

