

## Interview with Veronique Pinilla (UCB Pharma)

# Trends in Chiral Large Scale Purification Solutions from Industry Leader UCB Pharma

**Dr. Pinilla is a Senior Principal Scientist, Prep Chromatography at UCB Pharma in Braine l'Alleud (Belgium). She has been involved with prep and process chromatography since 2001. Her interests in prep and process include chiral chromatography especially by MCC and SFC.**

**Veronique earned a Ph.D. in organic chemistry at the University of Strasbourg (France) working on the "isolation of immunomodulators from plants used in Chinese traditional medicine", followed by a 2 years postdoc at the Cancer Research Institute in Tempe, Arizona (USA), working on the isolation of anticancer molecules from plants and marine organisms.**

**She is actively involved in implementation of SFC at UCB as the next generation tool for prep chromatography.**

### Phenomenex:

UCB is running a large scale Multi Column Chromatography (MCC) system yet there are relatively few large scale systems installed in the industry. In recent years no large scale processes have been introduced despite the fact that the percentage of chiral drugs is ever increasing. What do you think is the reason for that?

### Dr. Pinilla:

I'm not sure but I'm guessing that chemists are still very much focused on chemistry solutions and not on chromatographic ones. Chromatography is indeed increasing in spin-off companies to increase speed or in generic industries to bypass patents!

### Phenomenex:

Compared to reversed phase chemistries there are relatively few chiral chemistries available for commercial scale purifications. Do the commercial scale chiral stationary phases currently available satisfy the customer needs in terms of variety?

### Dr. Pinilla:

There are quite a lot of chiral stationary phases (CSP) available for analytical work but not all of them are efficient for preparative use. So for preparative applications, there are just a few possible CSP options. These stationary phases are usually based on polysaccharide chemistry. Prep customers, like UCB, are always looking for new chiral selectors since we still have a small number of compounds that are not separated with the current CSP currently available.

### Phenomenex:

You are also working with supercritical fluid chromatography (SFC). Do you see your SFC work increasing next year? Or in the next 5 years? Do you see your other purifications increasing as well or decreasing due to the use of SFC.

### Dr. Pinilla:

SFC is already increasing a lot. Since solvents are an issue for all the environmental reasons the purification industry already knows about, yes I do think SFC is a real option for the future. SFC technology still needs some improvements, even though the progress done during the last 3 years are tremendous.

### Phenomenex:

What is the biggest challenge that SFC needs to overcome to make it a widely used technique?

### Dr. Pinilla:

In order for SFC to be more widely accepted, I think the instrument suppliers need to lower the cost of the equipment, since Pharma companies are going through an important financial restrictive period. We also need to see a wider range of chemistries with smaller particle sizes with lower price. There is also a need to reduce the size of the SFC equipment without removing the easy-to-use parts.

### Phenomenex:

How important is the "Green Chemistry" concept within your company and what impact does this have on your chromatography work?

### Dr. Pinilla:

As with most companies, solvents are a real concern for UCB. Initiatives to reduce the impact on the environment are always welcome. SFC and the use of CO<sub>2</sub> is part of it, and solvent recycling is another option.

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### Phenomenex:

Which applications benefit the most from the advantages of SFC separations?

### Dr. Pinilla:

Right now, chiral separations gain the greatest advantages with SFC. Like in most Pharma companies, SFC is primarily used for chiral separations, but the development in achiral prep purification is increasing more and more.

### Phenomenex:

Nowadays, SFC is mostly used in the lab and small scale environment, do you think that this technology will become a production scale technology one day?

### Dr. Pinilla:

I hope so! It is used in the food industry at very large scale so there is no reason why we should not get to the point where we can replace solvent tanks with smaller CO<sub>2</sub> tanks in production.

### Phenomenex:

What is one change or improvement you hope to see in the SFC separations industry over the next few years?

### Dr. Pinilla:

SFC is so fast and efficient that to gain all the benefits of this technology, you need to use smaller particle size media. The availability and price of 5 µm particles is now the main drawback of SFC, as most SFC users are still using 20 µm particles.

All providers of achiral stationary phases (silica, reversed phase, etc...) did a great job during the past 20 years in order to improve particle size, reproducibility, efficiency, and even price, so I'm hoping that chiral phase providers will do the same job. Considering the financial constraints of the Pharma industries, we should act as partners. Chiral separations using SFC will reach larger scale work when efficient particle size media is made available, not only in terms of production capacities but also in terms of price.

### Phenomenex:

What is the optimum particle size for your MCC and SFC work?

### Dr. Pinilla:

For MCC work, 20 µm is a good particle size, but is not ideal for SFC work. For SFC work 20 µm is not efficient enough, 10 µm media is interesting, but 5 µm should be better.

### Phenomenex:

What are the major purification cost cutting efforts do you think corporations will employ in the coming years? Do you think that cost-cuttings will lead to increasing outsourcing to Asian contract manufacturing organizations (CMO's)?

### Dr. Pinilla:

Purification in R&D is an easy way to go fast and at that small scale it is cheaper than the other purification solutions. So CMO's are including chromatography as part of the synthetic work. It's not worthy in terms of timelines to consider Asia CMO's for a chromatographic step only at small scale purifications.