



JANUARY 29-31, 2019 - BOSTON

# INDUSTRY INSIGHTS

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# AN INTERVIEW WITH...



**Oleg Shinkazh**  
CEO

**CHROMATAN**  
SINGLE-USE COLUMN-FREE PURIFICATION

The CCP Summit has been partnering with ChromaTan for 2 successful years.

Ahead of the **3rd CCP Summit** in Jan 29 – 31, 2019, we have caught up with **Oleg Shinkazh**, CEO of ChromaTan to hear his thoughts on how continuous manufacturing is changing pharma's manufacturing world, and what barriers we need to overcome together to accelerate commercialization.

Oleg is the founder of ChromaTan and inventor of Continuous Countercurrent Tangential Chromatography (CCTC).

With 18 years' experience in R&D and technical support in the biotech industry, Oleg specializes in downstream processing/purification of human biologics.

In addition, he has extensive experience with all unit operations in the modern marketplace and has worked and collaborated with multiple industry leading bioprocess end-users, suppliers and academic institutions.

**HW:** It's a pleasure to work with ChromaTan at our CCP meeting again. I recalled we met at the very first launch of our Commercializing Continuous Processing community in 2017, and since then we've witnessed how ChromaTan and this meeting have grown!

**OS:** I am excited about the 3rd CCP Summit in 2019. I like that your conference is very focused, and I also think that it's a great idea to invite representatives from both the small molecule and biologics continuous space. During the last meeting it was inspiring to hear about the lessons with small molecules – it definitely impacted the way I am now thinking about the implementation of continuous in the biologics space.

***"I believe in open collaboration and candid sharing – especially for new technology adoptions. I think most companies who are engaged in CM have acquired some knowledge, but it's still very much fragmented and we need to harmonize our approach and establish common industry standards."***

**HW: So how do you see differences play out for small molecules vs biologics in the CM space?**

**OS:** There is clearly a different set of challenges for continuous processing in biologics – we are dealing with liquids as opposed to dry powders and pellets, and inevitably there are more process steps to handle.

Also the instrumentation for implementing PAT and system integration are very different. However, the QdD approach as well as the regulatory lessons learned in the small molecule space are highly relevant and applicable.

**HW: Can you share with us what's new with ChromaTan and what's the plan for 2019?**

**OS:** We've been very busy focusing on commercializing our Continuous Countercurrent Tangential Chromatography (CCTC) platform.

As you know, last year we received a \$2.5 million contract from the FDA to develop a fully integrated end-to-end continuous downstream process.

Our team has been working non-stop to execute on the delivery, and we have some very exciting data to share with the CCP community next January, showing significant promise for CM.

We have also been working on launching the CCTC platform to market in 2019, as well as engaging with our biopharma end users in R&D collaboration projects and contracts. We believe that these types of engagements can significantly de-risk the launch of new products in our space, as well as help spread good-will and generate buzz in our community.

**HW: We've been witnessing the CM's activities since 2017 – how would you describe the market environment right now?**

**OS:** There has been a lot of encouraging news from the industry. Several CM platforms are being scaled up to clinical manufacturing, and large players such as Merck, Pfizer, BI, Sanofi and Bayer are making significant investments into the space.

In fact, I am hoping to once again hear from a lot of them at your event! It's also reassuring that a number of larger suppliers are committed to CM, and launching continuous manufacturing platforms for both upstream and downstream operations.

***"Several CM platforms are being scaled up to clinical manufacturing. Merck, Pfizer, BI, Sanofi and Bayer are amongst the large players making significant investments into the space."***

In addition, the FDA has offered pivotal support for CM, reaching out to the industry and providing confidence to both suppliers and end-users that they are fully behind the efforts to modernize bio-manufacturing.

I am optimistic about integrated CM in biopharma, yet it's quite clear that we have a ton of work to do to make it a reality.

I think most companies who are engaged in CM have acquired some knowledge, but it's still very much fragmented and we need to

harmonize our approach and establish common industry standards.

This is why I think that in order to truly change the paradigm and accelerate CM adoption, developing effective partnerships between suppliers and end-users are absolutely key.

A greater degree of knowledge sharing between the major players, and through that - the development of seamless control / integration capabilities for CM are the next step. In addition, I believe it's also crucial to develop effective CM training programs for existing employees as well as the future generations of engineers. Inclusion of CM in the academic laboratories and class curriculum would go a long way towards helping implementation in both process development and at manufacturing scale.

At ChromaTan we embody this philosophy. We are always discussing ways to collaborate, and have executed a number of key partnerships with suppliers, end-users, and academic institutions that have yielded great results for data generation, implementation of new materials, software integration, quality of manufacturing and other important matters.

We have also found that partnerships among suppliers can have a great effect on helping each other craft an effective marketing message. After testing and implementing a key technology from a strategic supplier we co-publish white papers and feature each other's work during conferences and other industry events.

**HW: I feel like the pharma world is finally embracing tech disruptions! That said 'change' is never easy. What's your best tip to our audience?**

**OS:** For companies who are looking to get into CM and to truly modernize their

manufacturing approach – you need to know that it's a major effort. There needs to be buy-in and commitment from senior management.

I've seen a lot of companies who try to get involved half-heartedly. Without setting up the right team with the right capabilities and resources, momentum can get lost quickly. If you're serious about implementing CM, make sure you're dedicating enough resources as well as very intelligent and committed people to support these activities.

Having said that – I am very optimistic about our ability as an industry to overcome these challenges. The momentum is building, and events such as the CCP Summit help our industry get together and explore this exciting new space in bio-manufacturing.



Is our Expertise Partner at the 3rd CCP Summit. Oleg will be sharing a talk on: **Integrated Continuous Bioprocessing Platform Development – New Data, Partnership strategies, Integration, and PAT**

- Steady-state CCTC data from multiple modalities
- PAT and manufacturing – overcoming challenges with effective partnerships
- Integration of multiple unit operations – challenges and successes and the path forward



**Take a look at the event guide** now for more on this session and the rest of the speaker faculty and program