



**TRENDING: NEW CDMO MODELS FOR  
YOUR CONSIDERATION (PART 1)**



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# FROM THE EDITOR



**LOUIS GARGUILO**

*Chief Editor, Outsourced Pharma*

Something positive and of great importance also flowed through 2020: a handful of new and expanding business and service models at contract development and manufacturing organizations. CDMOs are changing, and providing drug sponsors – particularly virtual, and small to mid-sized organizations – with more, and it seems, improving options.

In this first of two parts, I present what might be the trend of the year: the Best In Breed model. Next, we take a look at what's billed as "the biggest CDMO in the world." Finally, I introduce a trend some believe should have evolved years ago: universities teaming up with CDMOs and other industry players to offer new opportunities for "close to home" outsourcing.

# OUTSOURCING TREND OF THE YEAR? THE CDMO SYNERGY SPRINT



**Louis Garguilo**

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The chief executives of two historic German CDMOs listen intently from their home offices. Logging in from New York, I'm painting for them a scene I envision regarding their recent collaboration announcement.

That announcement served as another solidification of an emerging trend in the global drug development and manufacturing outsourcing arena:

*CDMOs are entering strategic alliances for a best-in-breed response to the end-to-end service providers.*

How substantial are these new alliances? Will they benefit *Outsourced Pharma* readers looking for the best CDMO relationships and outcomes?

I first introduced this trend to readers in the editorial, [2 CDMOs Better Than All-In-One: The "Best-In-Breed" Trend](#), featuring an alliance between two California-based companies.



**Frank Mathias**

CEO, *Rentschler Biopharma SE*

"So," I say to Peter Soelkner, Managing Director, Vetter Pharma International GmbH, and Frank Mathias, CEO of Rentschler Biopharma SE, shedding a scintilla of cynicism via video conference, "I envision marketing folks in a beer hall, coming up with this news-generating announcement of 'a strategic collaboration enhancing services and skills along the biopharmaceutical value chain.'"

Never happened, says Soelkner, leaning into his screen. "That's not how this began."

"It's not what Frank and I wanted at all. When we talked about the relationship, one of the first things we addressed was how we'd seen enough of splashy company announcements to create news.

"We strive to have a compelling story, not driven by marketing, but by real performance. We've seen enough of where some overpromise and under deliver."



**Peter Soelkner**

Managing Director, *Vetter Pharma International GmbH*



## SO WHO IS DRIVING?

“Such a CDMO collaboration starts with a relationship at the top of the companies. This was the first driver,” says Mathias.

With that executive-level commitment in place, next was “understanding what our clients are expecting – What services can we offer them as best-in-class in the world?”

“Because of the complexity of the market we see now,” Mathias continues, “if other CDMOs can also do this, I believe we will have a trend in this direction. At the end, the client will be the winner.”

And what have clients said they need to win? Are global biopharma customers – who at least in the case of Big Pharma firmly guided a fractured CDMO space to increased M&A – now driving a similar *CDMO synergy sprint*?

Soelkner says it wasn't specific clients “forcing” these types of collaboration.

“However, there's a movement towards more sophisticated biopharmaceutical drugs,” he says. “That will include the third wave of biotech: Think gene and cell therapies, nucleotides, or orphan drugs. We know we must be extremely cost and time efficient for these customers to succeed.”

“That is really the writing on the wall,” Soelkner continues. “Customers weren't asking us to please join forces, but we were seeing more technical questions and specialized requirements; we needed to respond with the best possible services along those supply chains.”

Adds Mathias: “The two main drivers are time to clinic and time to market, and the costs associated with them. If we can do anything to reduce those, it will be an advantage for the clients.”

## PRACTICE MAKES PERFECT

Vetter and Rentschler are further down the road of practical integration than I had expected. Already, teams for both CDMOs are conducting joint meetings and reviews, which Soelkner and Mathias join.

The two executives agree it's been satisfying to see the progress these interdisciplinary teams have made in the last weeks and months. “It's an effective one-team mindset,” says Mathias.

Currently, two project managers from both CDMOs spearhead those teams, which consist of development, customer project managers, quality and technical disciplines, and other production and supply chain professionals.

“When all those folks are at the discussion table, it's hard to tell who's working for whom. And both sides throw all necessary resources into the projects. We will use the entire strengths of both organizations, with an interdisciplinary power to get the work done,” says Soelkner.

He isn't shy about letting me know how many projects he'd like to see become a part of the joint relationship with Rentschler.

“Hypothetically and in an ideal world,” Soelkner says, “it would be great if all of our roughly 30 customer-facing project managers end up working jointly with Rentschler.”

Even prior to this tightened relationship, Vetter and Rentschler – some 40 miles away from each other in southern Germany – “shared” customers.

“When I was reading your [first editorial](#) on this subject of best-in-breed partnerships,” Mathias says to me, “I noticed that for the two CDMOs in California, proximity was an important element. We have the same situation, and we also share the same culture.”

“Already we work with clients for which we do API production, and Vetter is doing fill and finish. So one way for us to accurately measure if we are succeeding with our new alliance will be to see if we are more effective and efficient for those customer projects.”

## MERGED MANAGEMENT

Project managers for Vetter and Rentschler have begun working on “pilot projects with active customers,” defining “the mindset, specific milestones, and how best to run specific project plans,” explains Soelkner.

“What is our idea of steering committees, escalation modes – which you always need for complex projects – and other aspects of the client relationship? All of those things have been discussed on a mock-slash-theoretical level.”

“We informed two clients they are a bit of a guinea pig at this point,” he says with a smile, “but both companies had to think about it a couple of seconds

before saying ‘absolutely,’ when asked if they were interested in becoming a pilot project.”

“We are working with these two customers in the pilot plant stage: the first focusing on phase one and two, and the other in phase three, preparing for potential market launch,” explains Soelkner.

“Separately,” he adds, “what we found quite interesting was after our alliance announcement, we got calls from other service providers. They said, ‘You know we could have done the same thing together with you? Why not us?’”

“People think what we’ve started here is an important new option.”

Will it become an industrywide race to unite? If so, despite everything else going on in 2020, it might end up the outsourcing trend of the year.

## **ABOUT THE AUTHOR**

Louis Garguilo is chief editor and conference chair for Outsourced Pharma, and a contributing editor to Life Science Leader magazine. He studied public relations and journalism at Syracuse University (and holds a Master’s in English), and has 30+ years of international experience in business communications and development positions.

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# THE BIGGEST CDMO SHOW ON EARTH



**Louis Garguilo**

Chief Editor, *Outsourced Pharma*

*“Come one. Come all. See The Biggest CDMO Show On Earth.”*

I suppose it was inevitable.

After years of escalating one-upmanship in the CDMO industry (e.g., “the only one-stop end-to-end global CDMO”), it was only a matter of time before we got the ultimate, “biggest CDMO on the planet” announcement.

And quite an announcement it is.

It includes: a center for breakthrough medicines, discovery labs, a colony, a King of Prussia, and a 30-month campaign to raise an army of 2,000 foot soldiers, all funded by a “specialty investment company” to the tune of \$1.1 billion.

The mission: To (absolutely once-and-for-all) “alleviate the critical lack of capacity that is preventing patients from accessing critically needed cell-and-gene therapies.”

And that’s critical.

So I asked for and received more details for *Outsourced Pharma* readers, from Audrey Greenberg, co-founder, Board Member and Executive Managing Director for *The Discovery Labs* (see below).

She provided me more specifics on the new CDMO, including a particular interest we’ve been pursuing here at *Outsourced Pharma*:

*What equipment, processing and manufacturing set up is needed in a new cell-and-gene service facility, and exactly what services need be offered?*

## THE PLAYERS DEFINED

Before we get to our discussion with Greenberg, for clarity I’ll quickly define the top five players (there are more). Also, based on my personal experience with large, economic development deals, I’ll add two players I believe must have or will have a role.



**Audrey Greenberg**

Co-founder, Board Member and Executive Managing Director, *The Discovery Labs*



1. The Center for Breakthrough Medicines – the name of the CDMO to be built and outfitted, described demurely as: “The World’s Largest and Most Advanced Single Solution Cell and Gene Therapy Contract Development and Manufacturing Organization. Period.”
2. The Discovery Labs – a “platform” company that builds world-class cGMP manufacturing facilities, turnkey laboratory solutions, critical materials and office space, all supporting the biotech and pharma industry – particularly in cell and gene therapies.
3. King of Prussia, PA – no, not a real king as alluded to above, but the Philadelphia-area location of a prototype for a global rollout of The Discovery Labs.
4. THE COLONY – yes, sort of as described above: a gathering of custom built discovery labs, “breakthrough funding” for research agreements, including housing for the world’s leading “iconic experts” in cell and gene therapy. THE COLONY (colonial in its insistence on all caps), will be established by The Discovery Labs and adjacent to the new CDMO.
5. Deerfield Management – the financiers, described as a management firm for advancing healthcare through “investment, information and philanthropy.”

Not Listed in the press release or mentioned by Greenberg, but again based on my assumptions:

- ▶ *The Governor of PA and whole lot of regional/local politicians* – any deal of this announced magnitude would have included political suasion on multiple levels.
- ▶ *State/Local Economic Development Agencies/Authorities* – organizations utilized by those politicians to grease the wheels of investment and employment, usually via a surfeit of grants, loans, tax breaks, and other measures.

## MORE ON EQUIPMENT AND TIMING

To be clear, this is how I’d summarize this:

A to-be-constructed/outfitted CDMO has signed a lease for a 680,000 square-foot facility [aka the biggest in the world for its purpose] in a “prototype location” that plans to employ 2,000 PhD-scientists, manufacturing experts, lab technicians and support staff within 30 months.

So while one and all cannot actually come and see the show just yet, biopharma companies are being told: Tickets for capacity and services starting the end of this year are now on sale. (I point this out because the press release seems to confuse present and future tenses at times.)

*The Center for Breakthrough Medicines* plans to provide customers from early stage through commercialization, once up and running:

- ▶ preclinical through commercial manufacturing of cell and gene therapies, and component raw materials;
- ▶ process development, plasmid DNA, viral vectors, cell banking, cell processing, and support testing capabilities (all under one roof);
- ▶ lots and lots of capacity (under that roof).

“We’re investing in the latest technology to provide our clients with the most up-to-date manufacturing equipment,” says Greenberg.

“We will deploy single-use bioreactors for suspension and anchorage-dependent processes, including pall, iCellis, GE Xcellerex, Sartorius, and Thermo technology.

“Downstream bioprocess will be heavily reliant on novel resins and single-use columns. State-of-the-art analytics and fill-and-finish technologies will also be provided.”

Greenberg further elaborated:

“*The Center for Breakthrough Medicine* is located at *The Discovery Labs King of Prussia*, which includes a former GlaxoSmithKline West campus. We are renovating the massive 1.6 million square feet site, and beginning construction of the CDMO immediately.”

I asked for more on timing.



“The first suites will be completed later this year, followed by commissioning and qualification,” replied Greenberg. “Of course, exact timing will be based on the process and client requirements.

“Beyond this year, we anticipate standardized spaces to be delivered every six months thereafter, until the facility is completely fit out.”

In total there will be 86 suites – 36 for cell therapy processing; 10 for plasmids production; 20 for viral vectors production; and 20 for testing, process development and cell banking (or the storage of live cells needed for future batches).

Greenberg explains the suites will have a modular design, “so they can adapt to a changing client base and future advancements in production.”

### **MORE THAN EQUIPMENT AND SERVICES**

But Greenberg has more than equipment on her mind. She’s also focused on THE COLONY. I’ll remind readers this is the planned co-location of custom-built discovery labs, fueled by funds for research programs, housing, and the hoped-for relocation of “the world’s leading iconic experts in cell and gene therapy.”

As I recently wrote regarding separate, announced plans for a cell and gene CDMO led by Harvard and a cast of others in the Boston area:

“Harvard and company deserve kudos for bringing together [at one location] the various players – universities, hospitals, drug and therapy developers, CDMOs, and equipment providers – all to serve a localized biotech community, and ultimately patients.”

Those same accolades apply here, but the difference of course is scale: Greenberg and associates are building and thinking big. Real big.

Finally, but of immense importance to our drug development and manufacturing outsourcing industry, there’s a second sentiment with echoes from the Harvard – and indeed other recent – news:

The U.S.-based CDMO, newly catalyzed by the need for emerging cell and gene therapy support services, is again on the rise.

### **ABOUT THE AUTHOR**

Louis Garguilo is chief editor and conference chair for Outsourced Pharma, and a contributing editor to Life Science Leader magazine. He studied public relations and journalism at Syracuse University (and holds a Master’s in English), and has 30+ years of international experience in business communications and development positions.

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# A HARVARD ASSIST FOR CELL AND GENE BOTTLENECKS



**Louis Garguilo**

Chief Editor, *Outsourced Pharma*

Bottlenecks and backlogs in development and production of cell and gene therapies.

Harvard to the rescue.

Actually, Harvard *with partners*, such as MIT, well-known hospitals including Dana-Farber Cancer Institute, and companies familiar to *Outsourced Pharma* readers, such as Fujifilm Diosynth Biotechnologies and Cytiva.

They and others are part of a \$50 million [Center for Advanced Biological Innovation and Manufacturing](#), which will be constructed at a location in Massachusetts soon to be announced.

I've been able to gather more detail on this new center and its objectives. And we'll use an analysis of this news as a catalyst to investigate the overall cell and gene industry from our particular standpoint of CDMO assistance. We'll focus on the equipment and services biopharma companies need to progress their programs to commercial products and therapies.

According to Harvard, while there are "many commercial contract manufacturing organizations, shared lab spaces, and even small manufacturing spaces at universities and hospitals in the U.S., this is a first-of-its-kind facility in three respects":

1. The intention to produce both cGMP grade cell and viral vector products in a more streamlined way and within the same facility;
2. The unique partnerships between industry, academia and leading area hospitals;
3. The partners' aspirations to provide services to researchers and biotech start-ups and advance this new area of medicine through collaboration.

The university states: "From gene therapies to cancer immunotherapies to cancer vaccines, recent biomedical advances have redefined what is possible in medicine. Yet, despite the advent of such transformative therapies, bottlenecks in the discovery pipeline and backlogs in production remain press-



**Emmanuel Ligner**

President & CEO, *Cytiva*



ing challenges that hamper the rapid and widespread delivery of new lifesaving treatments to all patients who stand to benefit from such critical innovations.”

I asked Harvard for more detail on those production bottlenecks, and precisely: What equipment must go into a new facility of this kind? What services does the Center – or a more typical CDMO – need to offer biotechs?

The university immediately put me in touch with Cytiva to help answer my questions. That led to an informative and open conversation with CEO & President Emmanuel Ligner.

### NOT QUITE A CDMO

First off, the Center will not serve as a typical “CDMO”; the plan is to operate as “an independent, nonprofit organization.”

However, says Ligner, “We have every intention to help the local biotech.” The Center will form a committee to review “the scientific interest of some of the small biotechs in the Massachusetts environment.”

“As you know, it’s a geography boiling over in terms of innovation. There’s a need for space, product, and access to patients. The Center will be the right place to come for a local biotech.”

For *Outsourced Pharma* readers, encouraging from from our vantage point is the news of this direct pairing of members of the drug development and manufacturing outsourcing industry, and the universities and hospitals.

It has been a delimiting defect that CDMOs and universities – who share the biotech start-up as a partner and customer – have not figured out how to engage in more collaborating, co-investing, and co-developing of potential new drugs and therapies.

Employing all those partners and assets, we are told the Harvard center will “explore and develop innovations in cell and gene therapy; advance biologic discovery and manufacturing; and accelerate developments in immunotherapy, cell therapy and gene editing.”

## VALUABLE VIRAL VECTORS

Lets now turn to the premise of development and manufacturing bottlenecks. What exactly are we referencing?

The cell and gene industry has been on the move. Cytiva, for example, has garnered attention for its assistance in accelerating capacity for cell therapy, most notably in *China*. (A recent example is a large [Lonza factory in China](#) currently under construction.)

Here in the U.S., Thermo Fisher has [announced the opening](#) of a new “\$90 million viral vector CDMO site in Lexington, MA.” Michel Lagarde, executive vice president of Thermo Fisher Scientific, commented the “demand for new gene therapies has outpaced capacity.”

In Northern Switzerland, Novartis recently made news with this telling headline: [Novartis’s \\$90 million Swiss factory to help solve cell therapy bottleneck](#). (I guess \$90 million is what it takes nowadays.)

That facility is described as “a cell and gene therapy factory,” particularly to begin commercial production of its cancer cell therapy Kymriah in 2020.

Overall, Novartis is said to be investing some \$500 million in new facilities around the world “to address production bottlenecks.” According to Reuters, drug companies including Novartis and Pfizer plan to spend a combined \$2 billion “building out gene and cell therapy manufacturing.”

Given these and other announcements, I ask Ligner if any “bottlenecks” aren’t already being adequately addressed.

“Let me approach this differently,” he replies. “The number of clinical trials in gene and cell therapy have exploded over the last few years. There are a thousand-plus clinical trials ongoing globally, so we must do more than just create more capacity.

“Many of these new therapeutic approaches require the production of viral vectors. Viral vector manufacturing today is cumbersome, and the yields are poor. So the demand on viral vectors – and their price – is extremely high. This is why you see a huge amount of investment in that field.



“If you are a startup biotech in need of viral vectors today, the waiting list may be pretty long. It makes sense the industry continues to invest, including in the CDMO area.”

Therefore, confirms Ligner, viral vectors make up the bulk of those talked-about bottlenecks for cell and gene research, development and commercialization.

“If you think about cell therapy, you modify genetically the cell of the patient *ex vivo* using a viral vector. In gene therapy, that modification occurs in patients. But typically in both cases you need a viral vector to carry the gene inside the cells, either *ex* or *in vivo*.”

### ARE YOU EQUIPPED?

And of course for viral vector manufacturing, says Ligner, there is a list of equipment that can and needs to be installed and utilized. We will cover this equipment in detail in part two.

Today larger biopharma confront the choice of building facilities or outsourcing for those viral vector (as well as related) services. For smaller companies, it's more a decision to accurately determine if your CDMO has the right skills ... and that requisite equipment. And get into development and production schedules.

For now, Harvard and company deserve kudos for bringing together the various players – universities, hospitals, drug and therapy developers, CDMOs, and equipment providers – all to serve a localized biotech community, and ultimately patients.

Says Ligner: “This consortium provides the opportunity to develop and accelerate the next generation of technologies to alleviate bottlenecks in manufac-

turing. For cell and gene therapies to reach their full potential, we must deploy a dual approach of expanding capacity, while developing new technologies.”

hances are – and sources are already telling me as much – this model will be replicated in other biotech clusters around the U.S.

[Click here for part two](#) of our discussion with Diana Francis, China Biopharma: Recognizing The Past, Recasting The Future.

### ABOUT THE AUTHOR

Louis Garguilo is chief editor and conference chair for Outsourced Pharma, and a contributing editor to Life Science Leader magazine. He studied public relations and journalism at Syracuse University (and holds a Master's in English), and has 30+ years of international experience in business communications and development positions.

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