Advanced Pharmacopeia

B2B Life Science / Technology Seed Stage Startup

developing cutting-edge analytical solutions for Pharmaceutical/Biotech & CRO/CDMO firms

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Academy of Contemporary HPLC

Educational, Consulting & Startup HPLC Company

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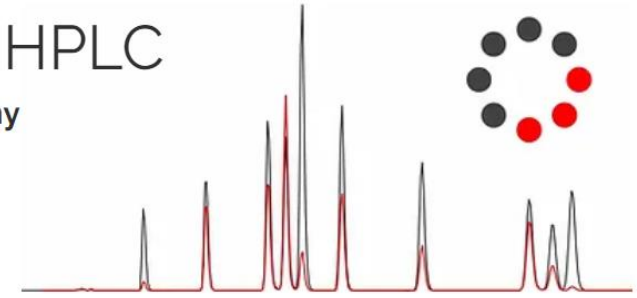


Problem

Today's pharmaceutical & biotech industries suffer from a severe lack of truly modern: high-performance and cost-effective – analytical HPLC* methods for drug quality control.

***HPLC** (high-performance liquid chromatography) is the principal technique for drug quality control.

1. Just imagine – with **1'500+** FDA-approved drugs and **20'000+** medications in total on the world market, the existing Pharmacopeia contains just about 170 monographs, which is **≈10%** and **>1%** as compared to a total amount of approved APIs & medications on the market, respectively.

2. It may sound shocking, but it's true: the most of HPLC methods listed in Pharmacopeia have been developed 20-40 years ago, and from today's point of view are extremely outdated: barely tolerable in terms of performance and extremely cost-ineffective.

3. More than that, **Pharmacopeia monographs** concern the analysis of pure drug substances only, and they cannot be applied for controlling drugs in various drug formulations and novel delivery forms (ointments, suppositories, syrups, gels, liposomal delivery formulations, etc), as well as to control drugs in combination medications.

These problems are still somehow solved by large pharma companies, but it comes at a very high cost of new laboratories, equipment, and high salaries for the staff. Besides, the results can often be suboptimal.

As for the smaller pharmaceutical companies and pharma/biotech startups, today they literally have no chance to get a modern cost-effective analytical solution that meets their needs quickly and at a reasonable cost.

Solution

The problem can be solved by developing the Advanced Pharmacopoeia (Ad.Ph.) – a renewable compendium consisting of modern: cost-effective and high-performance – commercial methods for controlling various drugs in different medicinal formulations.

At the growth stage is the compendium is supposed to be converted to a B2B software platform / database of the most up-to-date HPLC methods for pharma/biotech industry.

As compared with the existing Pharmacopeia, Ad.Ph. solutions will…

1. enable to analyze various formulations, media, novel delivery forms – instead of Pharmacopeia solutions capable of analyzing pure substances only;

2. be exceptionally reliable: robust and easy-to-transfer ones – instead of generally non-robust and hard-to-reproduce Pharmacopeia solutions;

3. be several times more cost-effective than Pharmacopeia solutions through higher throughput, general reliability and versatility;

4. cover much more APIs, especially the recently approved ones that are not mentioned in the existing Pharmacopeia.

It can include all types of HPLC methods most used in the pharma & biotech industries:

- assay HPLC methods (for APIs & excipients in various formulations);
- HPLC methods for impurity analysis;
- HPLC methods for forced degradation studies;
- chiral HPLC methods.

Market / Customers

The potential market:
all types of pharmaceutical & biotech companies, startups, and CRO/CDMO companies

Early stage customers:

1. Small pharmaceutical/biotech companies and startups
2. Small CRO/CDMO companies

Growth stage customers:

3. Medium-sized pharmaceutical/biotech companies
4. Large CRO/CDMO companies

Final objective: **5.** To reach top 30 pharmaceutical/biotech companies

Benefits to Customers

1. The highest cost-effectiveness: typical throughput of Al.Ph. methods will be 4-30 analyses/hour, whilst the average throughput of Pharmacopeia methods is 0.7-4 analyses/hour, i.e. Al.Ph. methods will be 5-8 times faster.

2. The highest versatility of Al.Ph. methods. While Pharmacopeia methods are intended for the analysis of pure drug substances only, Al.Ph. methods are specially designed to be suitable for analysis of various matrices (ointments, suppositories, syrups, gels, liposomal delivery formulations, etc).

3. De-risking of R&D process: no one can guarantee 100% success of a method development by an R&D laboratory – any HPLC method development may fail.
Such risks can be avoided by purchasing the ready-to-use Al.Ph. HPLC method.

4. Time savings: standard Al.Ph. methods can be supplied immediately.
Customized methods are supposed to be supplied within two weeks – which is unparalleled taking into account that at present moment the method development usually takes about two months or even more (up to several years).

5. Money savings: Al.Ph. methods will be sold at a certain fixed price of $2-5k per method which is quite less than the costs of their development in a typical R&D laboratory (about $10-20k per method or even more).

6. Flexible user-friendly approach: any Al.Ph. method can be customized according the customer's needs.

Scalability / Financial Projections

Scalability: every HPLC method is developed only once, but can be sold many times to all customers having the same or a similar problem.

Economic feasibility: in case of a hundred sales of a method the cost of its development becomes negligible as compared to the revenue.

With a price of $2-5k per HPLC method and the early need for hundreds of HPLC methods by dozens of small-to-medium pharmaceutical companies and startups, the Alternative Pharmacopoeia can become a profitable business that can bring in more than a > $100M just in first 5 years with good prospects for further scaling.

What happens when a customer asks for an Al.Ph. HPLC method?

1. If we do not have such method in Al.Ph., we - develop and verify a new HPLC method; - sell to the customer; - analyze the feed-back; make corrections if necessary; - add this method to the Al.Ph. (to be sold eventually as a standard method to any other interested customer).

2. If we have such method in Al.Ph., and customer is satisfied with the standard solution, we simply sell the method ($2-5k per each).

3. If we have such method in Al.Ph., and customer needs a tailored solution, we
- make necessary corrections of the standard Al.Ph. method; - sell the customized method at a higher price ($2-5k + $2-5k customization fee); - add customized method to the Al.Ph. as a separate method version (to be sold eventually as a standard method to any other interested customer).

Project Innovations

We have developed four key innovations, which are the cornerstones of this project from the viewpoint of the technology.

1. A novel quality standard developed for targeted HPLC methods named *CE.S.T.R.Us* (**C**ost-**E**ffectiveness, **S**uitability, **T**ransferability, **R**eliability, and **Usability**). The standard considers an HPLC method as a consumer product that has its consumer characteristics and relates the final quality of an HPLC method to a specific set of its critical quality attributes.

Such standard is essential for maintaining and continuously improving the quality of Ad.Ph. methods.

2. A novel approach to HPLC method development that enables to do it very quickly and faultlessly regardless of target analytes and matrix (named *S.Sp.O.* after the three main stages of the corresponding workflow (**S**olution, **Sp**ecificity, **O**ptimization).

3. A number of pre-developed ready-to-use Ad.Ph. method templates are designed for a number of classes of pharmaceutical compounds and various matrices. It strengthens the effect of *S.Sp.O.* approach ensuring the compliance of all template-based developed methods with *CE.S.T.R.Us* requirements.

4. A novel approach to control suitability and performance of the main element of an HPLC system called HPLC column. Such protocols are essential to control chemistry of an HPLC column to ensure excellent reproducibility (transferability) of all developed HPLC methods. These two protocols are named *RP/HILIC/CT-Test* and *IC/HILIC-Test*, correspondingly.

Why us? (Our achievements) / Customer early traction

Our achievements:

1. 500+ HPLC specialists from **70+ pharma/biotech companies** (including local divisions of such well-known companies as Novartis, Sanofi, MSD, Danone, Dohler) attended our courses on HPLC method development.

Though our focus was on consulting and education in the field of HPLC, we have developed and sold to our corporate pharma/biotech customers **30+ routine HPLC methods**, and that's what we have got:

2. 0% failures for 10 years of HPLC method development: we have never failed to develop an HPLC method if we signed a contract – regardless of an analytical task complexity.

3. 0% claims for 10 years of operation: all our customers were completely satisfied with our tailored analytical solutions.

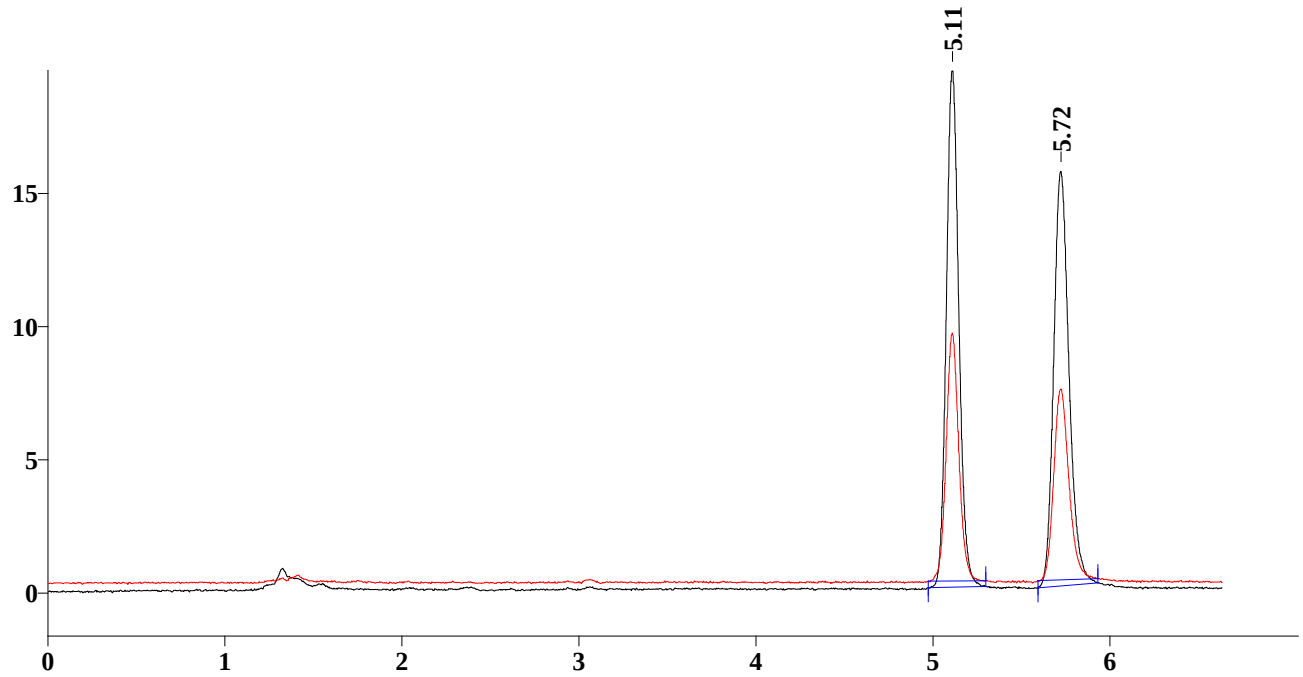
4. Partnership with HPLC column manufacturers: we have established warm business relations with the world leading producers of the best HPLC columns (Merck, Advanced Materials Technology, Regis Technologies, Teknokroma, Maisch, Helix). Also we have tested their product lines (the results of testing are available on our website), which is essential for HPLC method development.

Proof-Of-Concept

Below there are just three examples of our HPLC separations developed for: #1. **Kivexa** (Epzicom), #2. **Berodual** (Bronchodual, Duovent), **DuoNeb**, and **Combivent**, #3. **Broncholate Forte**.

The full portfolio of **30+ HPLC separations** is available on our website. It demonstrates the variety of approaches and HPLC modes we use to achieve the best method performance and cost-effectiveness.

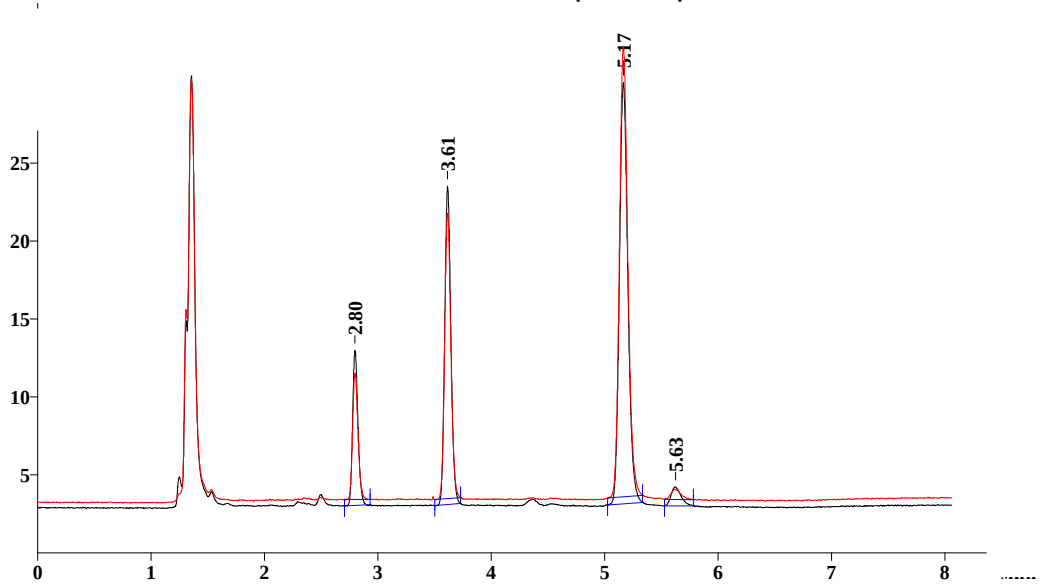
Combination Drug #1 Brand name(s): **Kivexa** (Epzicom) Lamivudine/Abacavir: **6 min., isocratic**



Kivexa: 1. Lamivudine, 2. Abacavir

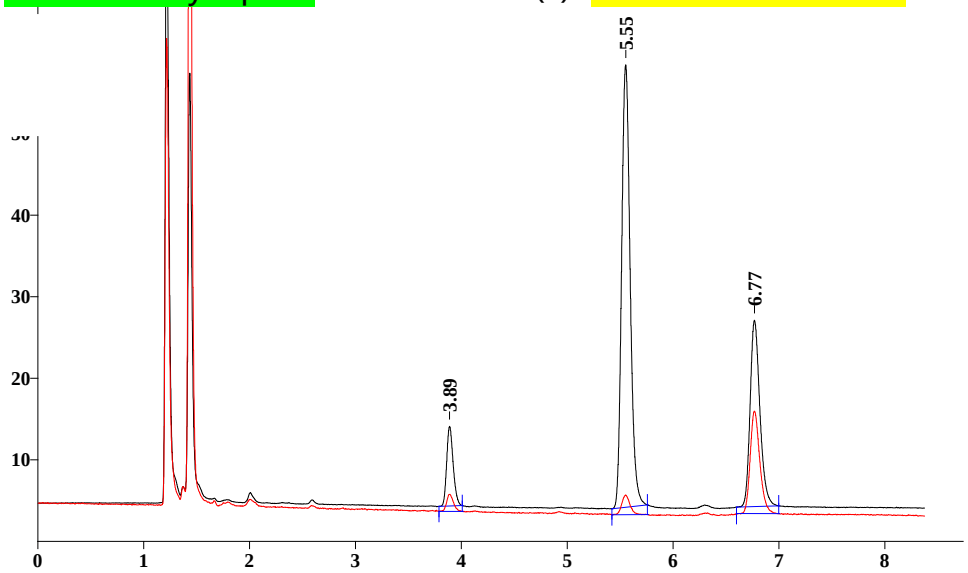
Combination Drug #2 Brand name(s): **Berodual** (Bronchodual, Duovent), **DuoNeb**, **Combivent**

Salmeterol/Fenoterol/Salbutamol/Ipratropium: **6 min., isocratic**



Mixture of Berodual, DuoNeb, and Salmeterol: 1. Salmeterol, 2. Fenoterol, 3. Salbutamol, 4. Ipratropium

Cold&Flu Syrup #1 Brand name(s): **Broncholate Forte** Diphenhydramine/Pseudoephedrine/Codeine: **7 min., isocratic**



Broncholate Forte: 1. Diphenhydramine, 2. Pseudoephedrine, 3. Codeine

Competition

1. The only competitor is the existing Pharmacopeia (USP, EP, etc.)

Possible exits

1. The best scenario: not to sell the business.
2. Exit scenario: acquisition by a large pharmaceutical/biotech or a large CRO/CDMO company.

Seed stage objectives

1. Submit the first version of the Alternative Pharmacopoeia consisting of at least 100 pharmaceutical/biotechnological HPLC methods **in 2 years.**
2. Sell 200 HPLC methods **within 3 years**.
3. Understand what type of customers brings in 80% of the profit (and to focus on them).

What we would like to have from a strategic investor

1. A seed round investment $800k:
- $300k investment in infrastructure (new laboratory equipment, HPLC columns, standards, reagents, etc., laboratory/office rental for 3 years);
- $500k investment in a team (3 years at a minimum burn rate).

2. Help with an access to a network of pharmaceutical & biotech startups / small-to-medium companies / CROs (CDMOs) who can be the first buyers of the Ad.Ph. methods.

About us

14 years of entrepreneurship & **25 years** in R&D – that is our general background.

For 14 years we have been entrepreneurs providing cutting-edge technologies of chemical analysis for local divisions of pharma/biotech & food companies, training & consulting their R&D analytical units.

In a harsh competition we spent years to perfect technologies we used to sell and teach. In HPLC we have developed a series of disruptive industry-specific approaches as well as unparalleled courses for R&D analytical departments of big pharma/biotech & food companies.

Such well-known companies as Novartis, Sanofi, MSD, Danone, Dohler were among our customers.

More than **500+** R&D professionals from **70+** pharmaceutical/biotech companies have attended our courses on HPLC assay development.

Konstantin Sychev has earned his Ph.D. in 2004 working with Vadim A. Davankov - the world-renowned HPLC scientist, the inventor of Chiral HPLC.

Konstantin Sychev: Founder. **Credo:** Insight-based innovations. **Skills:** Expert in HPLC technology development & coaching. Business development. Author of courses & 4 books on HPLC. **Background:** 25 years in pharma & food industry. 14 years of entrepreneurship. **LinkedIn:** https://www.linkedin.com/in/konstantin-sychev-b3758577/

Evgenia Okunsky: Co-Founder.
Credo: Feedback is everything.
Skills: Lab management. Quality management.
Background: 10 years in pharma industry.

- We are very realistic, keeping both feet on the ground, and very focused.
- We have an experience of building a non-standard business from the ground up & maintaining it for 14 years. We are flexible & adaptable to market needs.
- In our specific field we are super professionals teaching other professionals.
- We have a deep insight into industry & vision of the future technology.
- We are versatile researches in any field, be it life science or business. We are exceptionally strong in formulating, prioritizing and checking multiple hypotheses.
- We are not ego-centric; we want to build the business with our partners.

HPLC

75 endorsements

Chromatography

Endorsed by Anatoli Ch

63 endorsements

Analytical Chemistry

Endorsed by Anatoli Ch

58 endorsements

R&D

33 endorsements

Chemistry

32 endorsements

Life Sciences

30 endorsements

Summary / Contacts

1. **B2B** Life Science Seed Stage Startup
2. Customers: **Pharmaceutical/Biotech** & **CRO/CDMO** companies
3. The market is big and well-developed. The product is in demand
4. Excellent scalability is in the core of the whole idea
5. Low risks: startup can be sold to a large Pharmaceutical/Biotech or CRO/CDMO company

6. Our innovations are game-changing in terms of HPLC method cost-effectiveness, performance, and durability.
7. All necessary novel technologies and approaches are already developed and tested. They have proved the track record in the fail-safe development of the most cost-effective and durable commercial HPLC methods.

8. We have a chance to become a first-in-category life science company shaping the future of the market of pharma/biotech analytical methods (and defining prices on this market).

Contacts

Do you want to know a bit more? Please do not hesitate to contact us – we will be glad to talk.

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