

Medicon Valley Alliance

Drug Delivery Initiative

- *Proposal for Steering Group on how to strengthen drug delivery research in Medicon Valley*

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Contents

Executive Summary and Project Visualisation	3
Introduction	4
Drug Delivery Definition	4
Rationale	5
Vision and Objectives	7
The Drug Delivery Secretariat	9
Funding Strategy.....	11

Executive Summary and Project Visualisation

Executive Summary

Visualisation of the project proposal

The report at hand provides the input for the third Steering Group meeting within the Medicon Valley Drug Delivery Initiative. The report presents a concrete proposal on how to strengthen drug delivery research in Medicon Valley in a long-term perspective and, moreover, outline the necessary steps to get there.

The report is structured in three key sections: 1) is describing the overall benefits of implementing the proposal, 2) is outlining the proposals' vision and objectives, and 3) is describing how the establishment of a Medicon Valley Secretariat is key to achieving the objectives.

In general terms, implementing this proposal will help to facilitate collaboration between academia and industry in working together on groundbreaking, multidisciplinary research aimed at improving the development of drug delivery technologies. The concrete outcomes derived from a successful implementation of the project is:

- *A significant increase in funds allocated for drug delivery research*
- *An operational organization facilitating improved collaboration between stakeholders from industry and academia*
- *Improved coordination of drug delivery education in Medicon Valley*
- *A vibrant drug delivery research environment organized around a formalized drug delivery organisation*

All of the above would contribute to the successful achievement of the mission: that Medicon Valley shall develop capacity to be recognized as the leading cluster worldwide in the field of drug delivery.

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How is it the vision and objectives achieved?

A Drug Delivery Secretariat is established as a three year project

The secretariat's mission will be twofold:

- 1) ensuring willingness and commitment among politicians as well as public and private stakeholders to realize the vision and objectives
- 2) foster increased collaboration and knowledge sharing between Medicon Valley drug delivery stakeholders' through various workshops, seminars and educational coordination.

What is the vision and objectives?

A Public-Private Drug Delivery Organisation is established in Medicon Valley

The organization established will ensure that that Medicon Valley develop the capacity to be recognized as the leading cluster worldwide in the field of drug delivery.

The organizational set-up is still undecided, however, the following core features will apply:

- 1) The organization will manage a significant pool of funds for drug delivery projects
- 2) The organization will brand Medicon Valley as a drug delivery hotspot worldwide
- 3) The organization will foster multidisciplinary projects between academia and industry

Why are we doing it? What is the rationale?

Expected benefits from implementing the proposal are increased growth, competitiveness and employment within the life science sector in Medicon Valley

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Introduction

The report at hand provides the input for the third Steering Group meeting within the Medicon Valley Drug Delivery Initiative.

The report presents a concrete proposal on how to strengthen drug delivery research in Medicon Valley in a long-term perspective and, moreover, outline the necessary steps to get there. The proposal has been written in response to the needs analysis conducted as well as previous discussions within the Steering Group.

The purpose of the last Steering Group Meeting is to get the Steering Group's buy-in on the outlined proposal and commitment to take the initiative further.

Reading Guidelines

The report is divided in three key sections:

1. The first section describes the overall rationale behind the drug delivery initiative. Hence, it outlines the overall reason *why* drug delivery is important and why this proposal should be implemented.
2. The second section outlines the long-term vision and the objectives for drug delivery in Medicon Valley. Hence, it outlines *what* the proposal is trying to achieve in tangible terms.
3. The third section presents a detailed proposal on *how* the vision and objectives will be realised, including an overview of costs and activities related to the establishment of a drug delivery secretariat in Medicon Valley.

The second and third part of the report reflects to a large extent the conclusions reached at the second Steering Group Meeting held July 1, 2010.

The report will be finalised with reflections on different alternatives for funding the establishment of a drug delivery secretariat in Medicon Valley.

Decisions to be taken by the Steering Group

It is expected that the Steering Group at the meeting will discuss and reach a decision on each of the following questions:

- Do the vision and objectives presented in this proposal reflect the ambitions of the Steering Group?
- Does the Steering Group find it realistic that the secretariat can achieve the outlined objectives?
- Should the drug delivery secretariat be established as a part of MVA or as an individual entity?
- Are the proposed deliverables for the secretariat realistic and achievable?
- Which of the outlined routes for securing funds for the establishment of the secretariat should be applied?
- Are the members of the Steering Group committed to support (either financially or in-kind) the establishment of the secretariat?

Drug Delivery Definition

The proposal at hand applies a broad definition of drug delivery as outlined below.

A drug delivery system is defined as a formulation or device that enables the introduction of an active pharmaceutical ingredient (API) to its site of action.

The overarching aim of any drug delivery system is to improve the efficacy, safety and compliance regarding the medicinal product. This can be achieved by implementing various drug delivery technologies that enable improved bioavailability, targeted delivery, or an alternative route of administration etc.

A drug delivery system should not exert a pharmacological effect in the absence of the API. In this context monoclonal antibodies (mAB)

represent a gray area as they have the ability to exert targeted therapy themselves. It must therefore be stressed that mABs can only be regarded as a drug delivery system if they are associated with an API e.g. by means of conjugation or as part of a liposome and hence that the possible pharmacological effect of the mABs alone is regarded as inferior. In medicinal products where the main pharmacological effect derive from the mAB, the mAB is the actual API and hence not a delivery system.

Though the primary goal of drug delivery technologies is to ensure better therapy, the technologies can also be implemented in other parts of the medicinal sector. The targeted delivery of drugs used in cancer treatment can be used to develop diagnostic tools for cancer and vice versa. The technology used in diagnostics might be similar to technologies used in drug delivery and to distinguish the two it is essential to investigate the purpose of the technology.

The implication of a broad definition of drug delivery is that the future initiatives will have a broad scope and be applicable for a wide range of academic and industry stakeholders. This will increase the likelihood of getting the initiative implemented and moreover add to the multidisciplinary and collaborative research approach.

Rationale

The Need for Focused Initiatives' to Develop Medicon Valley

The life science sector in Medicon Valley is not as unique and promising as for only a few years ago. During the last couple of years many biotech and medtech companies have closed and even more are struggling for survival and reducing their development activities to a minimum. The most important reason for this is that the competition for capital has increased during the financial crises and, moreover, that the framework conditions for venture funds today are less attractive in our region compared to other regions. In order to attract foreign venture capital in the future, Medicon Valley needs to build a focused attractive regional profile and concrete initiatives are needed to support the development of this.

The presence of big and medium-sized pharmaceutical companies is essential for the future growth of Medicon Valley. Pharmaceutical companies is today, however, placing a predominant part of their future growth outside the region and a very significant and increasing amount of the R&D is already placed outside Medicon Valley. Adding to that, a number of Medicon Valley's smaller pharmaceutical companies (Ferring and Nycomed) have moved their head-quarter away from the region during the last couple of years.

The life science industry in Medicon Valley is diminishing, fewer people will be employed in the sector, the knowledge base will vanish and consequently the regional income base will be minimised.

Why Drug Delivery Represent a Future Key Area for Growth in Medicon Valley

The overall rationale behind the proposal at hand is that focused and ambitious public-private collaboration on drug delivery research can help to revitalize Medicon Valley in the long run. The rationale is based on the belief that drug delivery research will be one the most important areas for the future success of the life science industry.

Several indicators and trends listed below support this belief.

- The global drug delivery market has grown from an estimated \$26bn in 2000 to approximately \$60bn in 2006. The market has witnessed rapid expansion due to patent expiration of blockbuster drugs, stringent FDA regulations, an increased focus on the expansion of products' life-cycle, cost-effective production of delivery vehicles, and the emergence of a range of delivery solutions and hybrid platforms.
- Although the oral delivery system still dominates the drug delivery market, novel drug delivery technologies are rapidly emerging in the market mainly due to an increase in biological drugs.
- Drug delivery technologies help pharma and biotech companies to boost their revenues and enhance the efficacy of pharmaceutical products. These companies use drug delivery technologies

to quickly develop future commercial opportunities, to expand product lifecycles, and to take advantage of innovative delivery mechanisms in order to maximize drug sales.

As the mapping report shows, Medicon Valley is today in a good position to become a leading region on the future drug delivery market - if adequate actions are taken now. However, in order to become a world leading region on the drug delivery market, further investments and public-private research collaborations are needed.

Drug Delivery as a Unique Competitive Advantage

Countries like India and China educate a large number of highly skilled life science researchers every year, and due to relatively low costs and low salaries these researchers are highly competitive in comparison with their Medicon Valley colleagues. Hence, more and more generic research tasks are thus outsourced by the biotech and pharmaceutical companies to India and China.

Drug delivery innovation is, however, very complex and depends on vivid interactions between several life science sub-disciplines such as medtech and biotechnology and related disciplines such as ICT. The development of new innovative drug delivery technologies is thus calling on new collaborations between partners from different sub-sectors within the industry and academia, which requires intra-institutional trust and highly developed collaboration skills. The fact that the value and innovation most often will be created in collaboration between various companies, universities and hospitals in the region makes drug delivery R&D more difficult to copy and outsource to low cost life science clusters in India and China. This underscores that drug delivery can become a unique competitive advantage for Medicon Valley.

Expected Regional Benefits

Development and use of new and better drug delivery technologies will potentially spur establishment of new biotech and medtech companies as well as companies in the CMC manufacturing space and thereby expand the life science based labour market in the region. Additionally, already established companies in

Medicon Valley will benefit indirectly from an increased drug delivery research capacity in Medicon Valley and directly through collaborative industry-academia research projects.

Expected benefits from implementing the proposal at hand are significant increments in growth, competitiveness and employment within the life science sector in Medicon Valley. In more tangible terms the proposal at hand is expected to generate an increase in:

- People employed in the life science sector in Medicon Valley
- New companies established in Medicon Valley using novel drug delivery technologies
- Number of international recognized scientists working in Medicon Valley
- Foreign investments made in Medicon Valley life science companies

Comments to the Rationale

In order to fully validate the *rationale*, further studies are needed.

First of all a feasibility study will need to be conducted in order to validate that more funds allocated to drug delivery research will generate the expected value. The study shall moreover prove that investments going into drug delivery will generate more value than if the funds would have been directed to other research areas or divided between more life science related research areas.

Second, Medicon Valley's drug delivery strongholds need to be benchmarked vis-a-vis other clusters in the world as well as upcoming initiatives ongoing elsewhere in the world. This study will ensure that the stronghold developed in Medicon Valley will be unique.

It is proposed that both these studies are conducted by the established Drug Delivery Secretariat, which will be described in more detail later in this report. The ambition level and further design of the drug delivery initiative will depend on the results of these studies.

Vision and Objectives

This section outlines the vision and the objectives for the drug delivery initiative. In other words the section outlines *what* needs to be achieved in Medicon Valley in order to create the abovementioned regional benefits.

Drug Delivery Vision

The level of ambition for this initiative is very high. The vision for the drug delivery initiative is *that Medicon Valley shall develop capacity to be recognized as the leading cluster worldwide in the field of drug delivery.*

This vision was endorsed by the Steering Group at the second Steering Group Meeting, and the objectives presented below reflect this high level of ambition.

Key Needs Underlining the Initiative

From the needs analysis conducted as well as the discussions at the last Steering Group Meeting a number of needs have been identified:

- The need for a strengthened research environment within drug delivery in Medicon Valley
- The need for an institutional set-up for drug delivery research in Medicon Valley, which will further strengthen the branding of Medicon Valley as drug delivery hotspot worldwide, and an
- The need for an increase in collaborative projects between various stakeholders i.e. pharma, biotech, medtech and academia.

The key requirement for building a stronger research environment goes through ensuring that more funding is being earmarked to drug delivery research. The Steering Group assessed that approx. DKK 1 billion would be necessary over a ten year period to realize the vision and achieve the abovementioned benefits. Raising this amount of money is challenging and involve among other things that drug delivery is made a prioritized area on national research agendas in both Denmark and Sweden. Raising the importance of drug delivery on EU's research agendas would, moreover, further support the effort as well as obtaining funds from private funds and companies in Medicon Valley.

The second requirement besides securing additional funds for drug delivery research is creating an institutional set-up that can work to ensure maximum possible value for Medicon Valley.

The simple solution would be to distribute funds allocated to drug delivery projects through the existing channels for strategic research i.e. the Danish Council for Strategic Research in Denmark and Vinnova in Sweden. This set-up would, however, have some limits identified as:

- Difficulties in ensuring that Medicon Valley will develop to become a hotspot for drug delivery
- A potential lack of qualified projects proposed for funding
- Lack of one-point-of-entry for international partners wanting to collaborate

Basic Principles for the Institutional Set-Up

Due to the limits listed above an alternative institutional set-up will need to be established. Even though the concrete set-up has not yet been discussed in detail, the discussions at the last Steering Group Meeting revealed some basic principles that should underpin any institutional set-up designed.

In general terms, the Medicon Valley drug delivery set-up (organisation) should facilitate collaboration between academia and industry in working together on groundbreaking, multidisciplinary research aimed at improving the development of drug delivery technologies.

The drug delivery organisation should offer an innovative environment for drug delivery and the organisations activities should cover the following:

- Research and projects
- Education
- Conferences and workshops
- Publications and newsletters
- Network cooperation and partners, and
- Branding

As mentioned above a strengthened research environment is depending on the allocation of additional funds. The organisation established should play in a role in the managing these funds.

Projects may be initiated based on competitive tendering conducted by the organisation. Projects will always be multilateral (at least 3 partners) and typically involve 2-3 academic groups and 2-3 industrial groups, mostly combinations of big Pharma and SME's.

The idea is that partners benefit from projects first of all by the collaborative effort. The research projects will to a large extent focus on research that is difficult or impossible for the individual companies to perform in isolation.

The project contract agreements will describe in detail how to deal with IP etc. The basic principle could be that all partners stay owners of the background IP they bring and jointly owns the foreground IP generated in a project. If one of the partners wants to build further on the IP generated in a project, the other partners will have to be bought out. The organisation should have capacity to support the development of partner agreements.

The organisation should moreover play an important role in coordinating drug delivery education in Medicon Valley. In that respect the Medicon Valley Universities and the organisation may jointly offer a master's degrees and PhDs in drug delivery for regional and international students.

Last, the organisation should also take lead in organising a number of conferences and workshop's, prepare and distribute publications and newsletters as well as play facilitating role with regards to collaborations between various stakeholders.

All of the abovementioned activities will in the end contribute to branding Medicon Valley as the the leading cluster worldwide in the field of drug delivery

Two Alternative Models for Inspiration

Two models for a public-private drug delivery set-up in Medicon Valley were briefly discussed at the second Steering Group Meeting. The models are here shortly described as inspiration and to make the objectives more tangible.

The Medicon Valley Drug Delivery Institute

A Medicon Valley Drug Delivery Institute will be established with inspiration from the Dutch model, which is used for an international recognized organisation as Top Institute Pharma. Top Institute Pharma (TI-Pharma) is a public-private partnership established in 2006 after the Dutch model. The mission of TI-Pharma is to establish, support and manage public-private collaborations between academia and the (inter) national pharmaceutical industry in order to create 'health & wealth'.

Running costs for TI-Pharma are jointly financed by the industry (25%), academia (25%) and the governments (50%). Projects are financed individually by the same division to ensure public-private interactions at all levels.

If the Medicon Valley organisation is established after the Dutch model, the drug delivery institute will be a physical institute with facilities for research etc. The establishment of the institute will be rather expensive and will most likely need to be sponsored by private funds.

The Medicon Valley Virtual Drug Delivery Center

The Virtual Centre for Drug Delivery is a formal network co-operation between innovation and research groups at Medicon Valley universities, public and private companies, health care institutions, hospitals, and regional and governmental authorities.

The Virtual Centre for Drug Delivery is governed by a board with representatives from both public and private stakeholders and is managed by a director and a secretariat located in Medicon Valley.

The main difference between the Virtual Center and the Drug Delivery Institute is a less formal set-up and lower establishment costs as well as running costs. The virtual model can thus be seen as less ambition solution, which, however, may be easier to establish.

Comments to Visions and Objectives

The concrete public-private set-up has as mentioned not yet been discussed in detail by the Steering Group. It is therefore proposed that studies on the most feasible public-private

organisational set-up are conducted by the drug delivery secretariat.

Political willingness and commitment is essential for success when implementing an initiative of this magnitude. In order to ensure political willingness and commitment it will, among other things, be necessary to prove that the investment in drug delivery is more profitable than similar investments in other areas or smaller investments in several different areas. It will be a part of the drug delivery secretariats portfolio to deliver this proof as well as create political willingness and commitment.

The Drug Delivery Secretariat

This section presents a proposal on *how* the abovementioned vision and objectives will be realised by the established drug delivery secretariat.

The Drug Delivery Secretariat: Role and Tasks

A drug delivery secretariat shall be established for a period of 3 years. The secretariat's mission will be twofold, with the primary aim being ensuring willingness and commitment among politicians as well as public and private stakeholders to realise the vision and objectives, and a secondary aim to foster increased collaboration and knowledge sharing between Medicon Valley drug delivery stakeholders' through various workshops, seminars and educational coordination.

Ensuring willingness and commitment

Ensuring willingness among politicians and other stakeholders to prioritize drug delivery as one of the most important life science research areas call for a number of different tasks to be conducted. First and foremost the secretariat needs to generate proof that increased investments in drug delivery research will pay off for Medicon Valley. The secretariat will in that respect need to analyse the economic and societal importance of drug delivery for the future development of Medicon Valley vis-a-vis other life science research areas.

Methodologically this analysis is expected to be challenging, and the secretariat will most likely need external consultancy assistance to

accomplish it. Furthermore, the secretariat shall ensure that the methodology used corresponds fully with the prevalent methodology used by responsible authorities in Denmark and Sweden.

Willingness is, however, not ensured by establishing proof alone. The secretariat will need to work hard to ensure support from key stakeholders. The various change management related activities to be conducted by the secretariat include:

- Media and press coverage
- Individual meetings with key stakeholders
- Workshops with focus on economic and societal benefits from increased investments in drug delivery
- Development of easy read information material about drug delivery and benefits derived from increase in research
- Etc.

Nevertheless, before initiating the change management activities the secretariat need to know exactly what they are advocating for. Hence, an analysis of the best possible organisational public-private set-up needs to be accomplished.

Facilitating collaboration

The secretariat shall also from day one play a key role in facilitating increased collaboration between universities and private drug delivery stakeholders in Medicon Valley. As the needs analysis showed there are several quick wins that should be pursuit, such as:

- Organising a number of scientific symposia on different aspects of drug delivery
- Coordinate teaching activities within drug delivery among the universities in Medicon Valley (at masters and PhD level)

Moreover, the secretariat should also act as a drug delivery knowledge center in Medicon Valley and among other tasks keep track of key drug delivery stakeholders in Medicon Valley and their activities as well as monitor international markets for possible international collaboration. By doing that, the secretariat may also be in a position to propose and facilitate concrete

collaboration projects between regional and international stakeholders.

Management and Organisation

It is estimated that two to three full-time headcounts would be adequate for performing the abovementioned tasks. In addition, the secretariat will in some cases also bring in external consultancy assistance.

The profiles hired for the secretariat should jointly have experience within life sciences, regional economic analysis, and ex-ante evaluations of research interventions as well as be acquainted with political lobbying.

There are different ways to establish and anchor the secretariat, of which two is the most obvious:

1. The secretariat can be established as a part of MVA and thereby make use of the established infrastructure and the competences already existing in the organisation. In this alternative the secretariat would be established as an MVA project. The existing Steering Group would also be asked to act as Steering Group for the Secretariat.
2. The secretariat can be established as an independent entity to be hosted either at MVA or at the universities. The main difference from the first alternative is that a new organisation needs to be developed from the beginning, a board need to be established etc.

MVA has in its present organisation not the funds to initiate either of the alternatives. Both alternatives will hence need external financial support. There are pros and cons for both alternatives, which is outlined below:

Pro/Con Assessment	Pros	Cons
Secretariat as MVA project	<ul style="list-style-type: none"> • Easy to establish + swiftly operational • Utilize current infra-structure and competences 	<ul style="list-style-type: none"> • More difficult to secure EU (interreg support) since activities will be seen as MVA a part of MVAs normal services

Secretariat as individual entity	<ul style="list-style-type: none"> • New individual entity might be more visible • Organisation will be fully dedicated to drug delivery minimising risk of conflict of interest 	<ul style="list-style-type: none"> • Most likely a more expensive solution
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Drug Delivery Secretariat Costs

As mentioned above, MVA doesn't have free resources to finance the establishment of the secretariat and the continuation of the drug delivery initiative is therefore depending on securing funding from external sources.

The two alternative set-ups are priced differently and a rough and indicative calculation of both alternatives is provided below:

Project Costs (DKKm)	Secretariat as MVA project	Secretariat as individual entity
Staff	6	7
Consultancy	1	1
Office + equip	0,8	2
Workshops etc	1	1
Travel	0,5	0,5
Misc	0,5	0,5
Total cost (DKKm)	9,8	12

Explanation to the cost calculation:

- Staff costs for the secretariat as an individual entity is calculated with 3 persons in 36 months, which equals an average monthly staff cost of DKK 64.000 all included. Staff cost for the MVA project is lower since use of MVA staff creates more flexibility ensuring more efficient use of resources.
- Consultancy fee is estimated to a flat rate of DKK 1 million. Consultancy services are particular needed for the feasibility study.
- Costs related to office and equipment is estimated at DKK 2 million for the secretariat as individual entity. For the MVA project the DKK 0.8 million is calculated as 20% flat rate on staff costs.
- Travel and unforeseen expenses are calculated equally in both alternatives at DKK 0.5 million.

Comments to the Drug Delivery Secretariat

A highly valid question is 'what happens if the feasibility analysis show that drug delivery is not adding more value to Medicon Valley compared to other life science research areas?'

If that is the case, the vision and the objectives should be redefined accordingly by the secretariat, and a new plan should be build for the drug delivery initiative.

An alternative approach to funding is via private foundation such as the Lundbeck or Novo Foundation. Medicon Valley has limited experience with this approach and it is therefore not possible to assess the likelihood of success.

Funding Strategy

A complete assessment of the different funding opportunities that might be applicable for the project in its current form is a major task and since critical element of the project might be chanced as a consequence of the Steering Group Meeting this assessment has not been conducted yet.

Nevertheless, in order to get direction of which approach to apply the Steering Group approach to the fund raising strategy two overall approached is outlined below.

EU Funds:

There are two EU funding opportunities, which might be applicable for this project: EU's Intereg Funds and EU's Structural Fund. Both funds require co-financing from either/or public and private stakeholders. The major risk of this approach is that the project probably needs to be redefined according to the fund criteria and even then there is a risk that this type of project, which includes significant resources for lobbying, might not be approved.

Regional Development Funds:

The three regional authorities in Medicon Valley have their own regional development funds. Projects are eligible if they are aligned with the regional development policies. Co-financing is required from private stakeholders. If the regional authorities find the project relevant and valuable the bureaucratic risks are lower compared to the EU route.

Private Funds