Development of your pharmaceutical – do it right first time

Åse S. Mjelva

Senior Regulatory Manager

Our Vision

To be the BEST CRO in Northern Europe

- True full service; from early stage development to post-market
- 181 employees providing expert guidance to every aspect of a project - from one source
- Offices located in Norway, Sweden, Denmark, UK and Germany

Our Mission

LINK Medical is a full-service provider for the pharmaceutical and medical device industries.

Our mission is to be the strategic partner, guiding our clients through competence and evidence-based documentation to make optimal decisions which drive superior clinical outcomes.

Company Structure

• International Operations

- Full Service delivery of clinical trials (phase I to III, device and pharma)
- End to end Biometrics

• Medical

- Early stage development
- Medical Device
- Safety Reporting/Pharmacovigilance
- Phase IV studies/Real World Evidence
- Health Economics

• Regulatory

- Clinical Trial Submissions and Reporting
- Regulatory Affairs
- Product Life Cycle Management
- Medical Writing

The Complete Nordic Regulatory and PV Solution

ONE contract source for the Nordic/Baltic region

LINK Medical has highly qualified Regulatory, PV and QA resources in all Scandinavian countries

Through our partner Medfiles we offer a complete Nordic/ Baltic solution for post market regulatory and PV services

Our Experience

25 years experience

Over 50 active customers in Regulatory/QA today

High degree of repeat business – loyal customers for up to 20 years

Many LINK personnel have worked in large Pharma or for Nordic health authorities

Approx. 4000 single tasks contracted to LINK per year

Covering the whole Nordic/Baltic region

LINK Medical Quality Assurance

Our experienced and dedicated QA team can support:	Batch Releases
	Quality Complaints
	GDP QMS and Responsible Person
	SOP Audit
	Inspection support

Why work with LINK Medical?

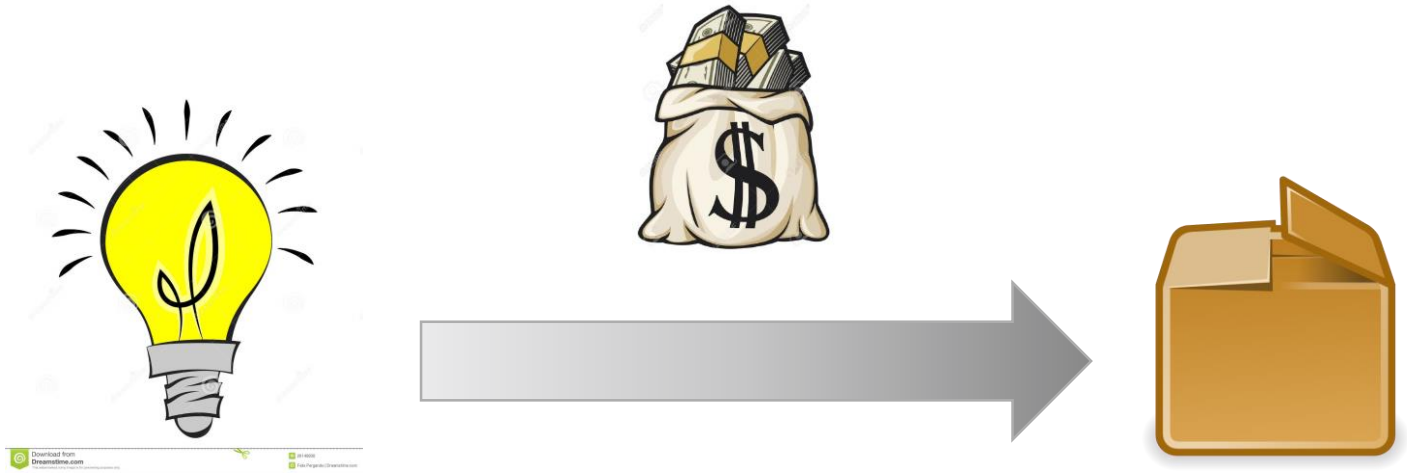
- Early Stage Development – optimised pathway to commercialisation
- Full Service Product Development
- End to end Biometrics (master users of Viedoc)
- 50+ Staff for Nordic Regulatory Affairs and Pharmacovilgilance
- Health Economics Real-World Evidence

Agenda

- The basics
- Some general pointers
- How to get where you want to
- Take home message

The basics

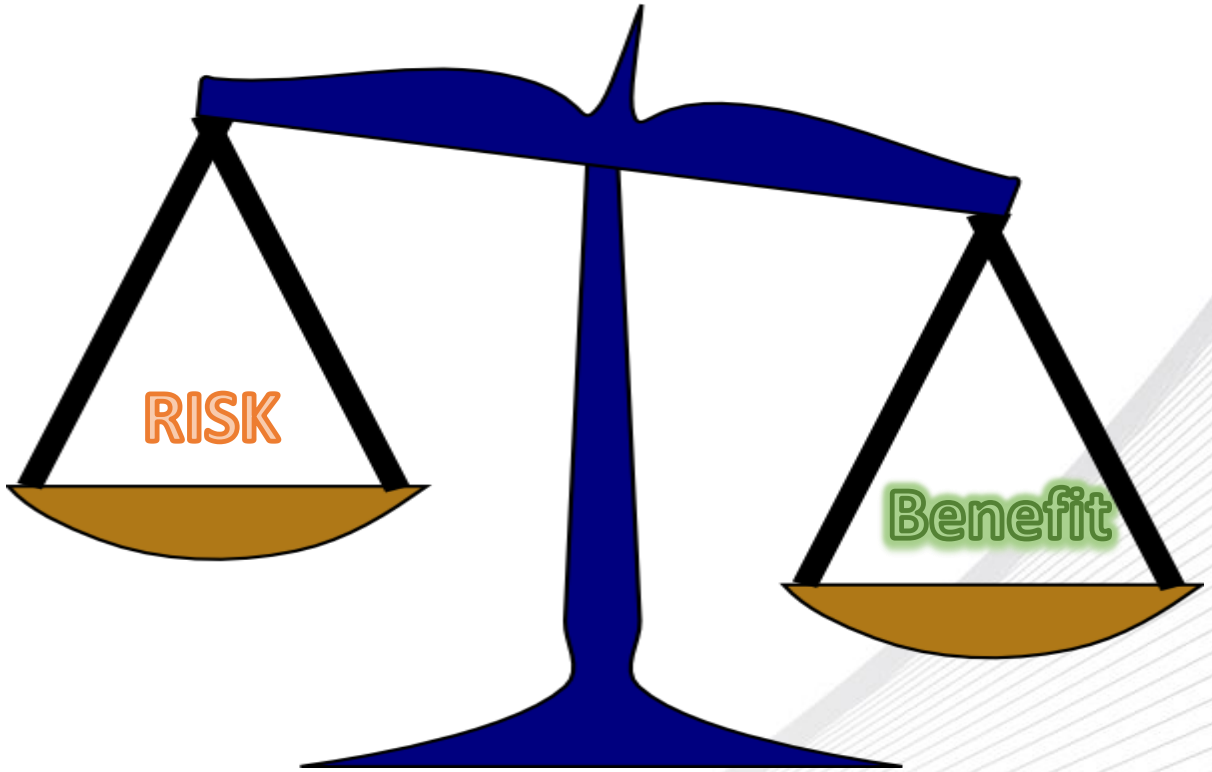
- What do you have to fulfil and how do you do that



What is it all about?

A medicinal product must

- fulfil certain quality requirements
- be effective
- have a favorable risk/benefit profile

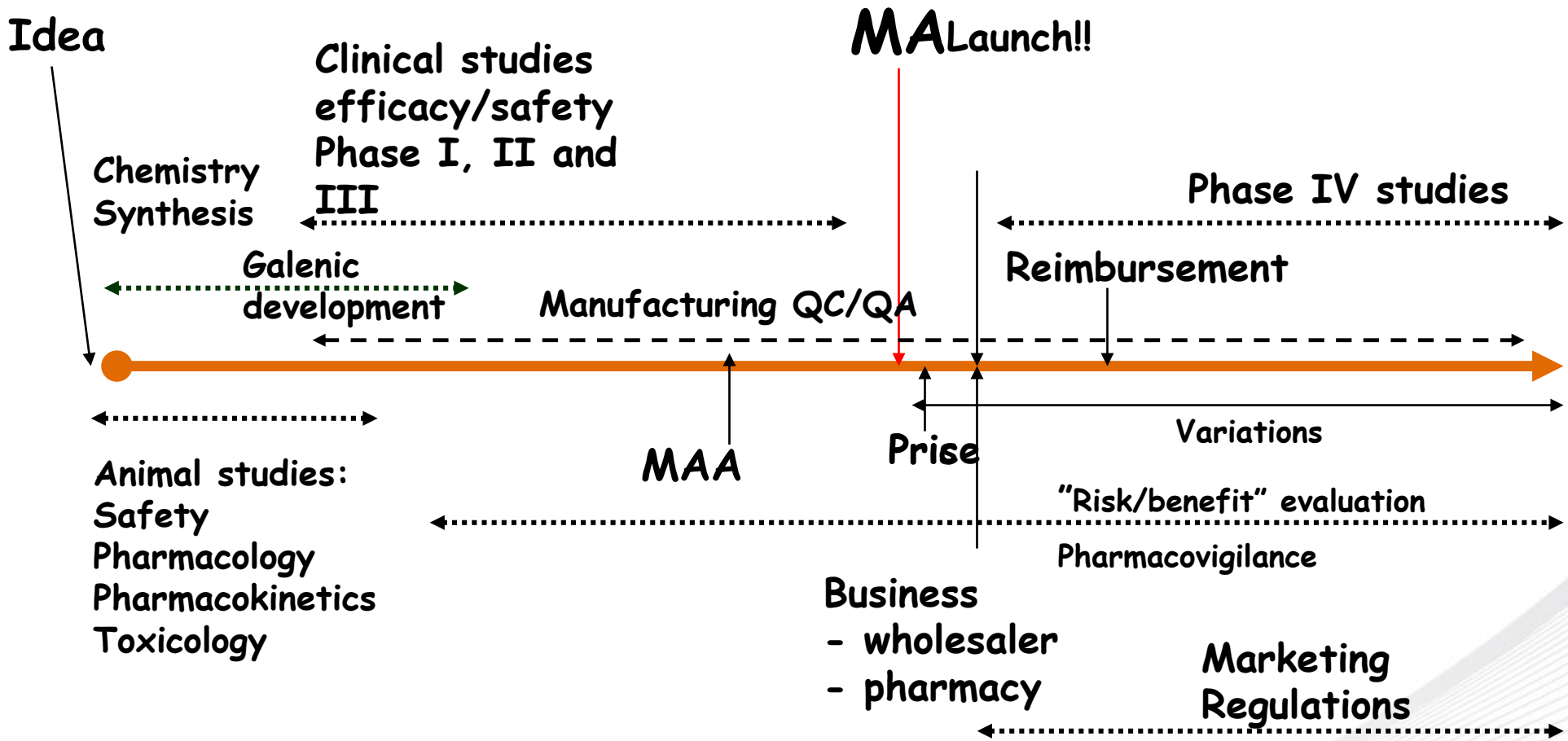


Regulatory

- If the end user is a patient – there is a set of rules you have to follow
- What rules and regulations apply?
  - Depends on your product
  - Depends on your market

Drug development and follow-up

Hauge og Thomassen: Legemidler og juss, Fagbokforlaget 2008



Some general pointers

- What should always be on top of your list?
- What should you always be aware of?

Where are you – and where are you going?

What is not documented does not exist

- “If you don’t have the time to do it right, when will you have the time (and money!) to do it over?”

How to get where you want to

- Decide where you want to go
- Why is it important to document
- When should you ask for advice
- Who should you confer with
- How do you document

Market

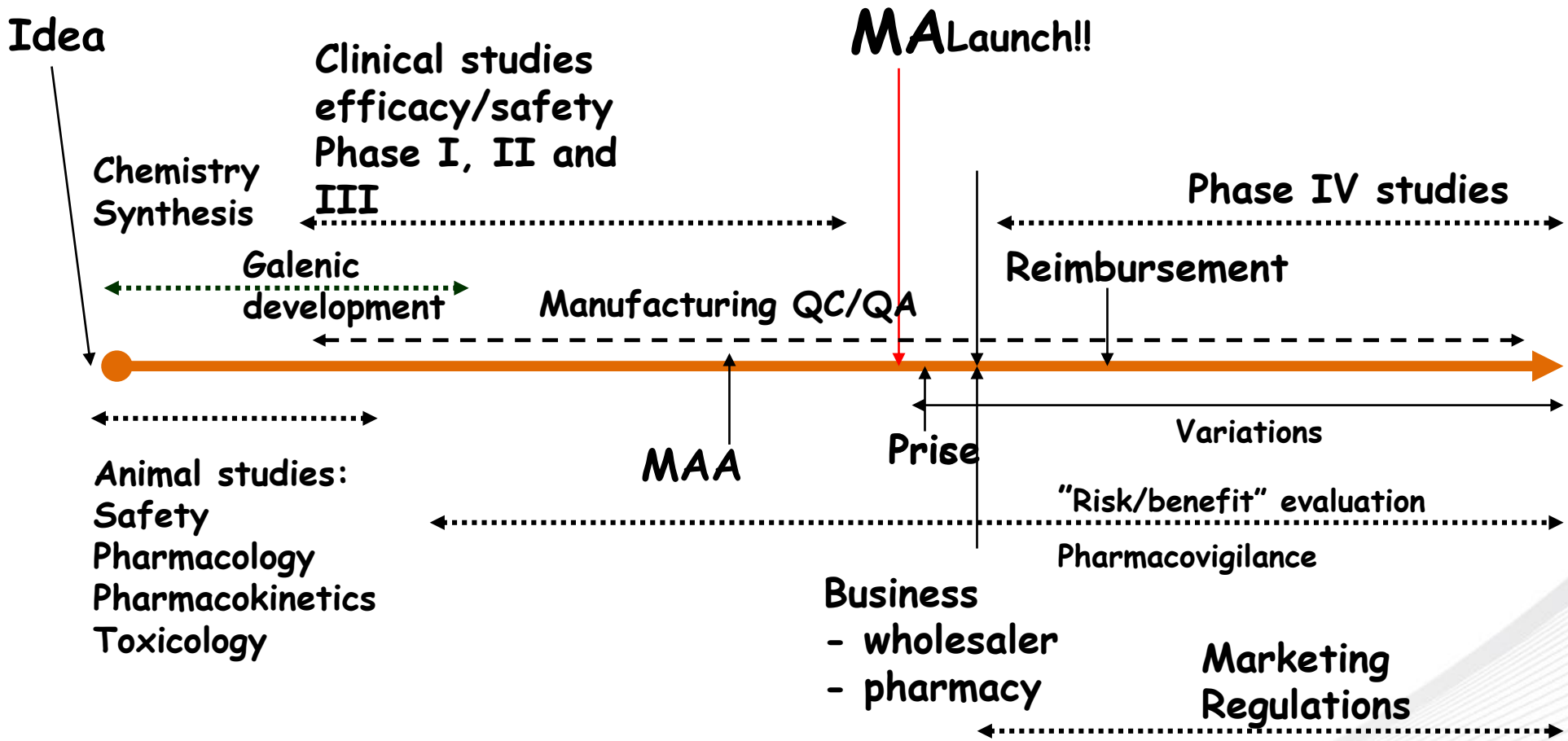
- Du you have a market?
- How many patients?
- What is the current standard treatment?
  - Is your treatment better?
  - Cheaper?
  - What is your benefit?
- Price – can you make a living?
- Are you bringing an increased value to patient and/or healthcare professionals
- Reimbursement
- Different situations in different markets

Where are you going?

- What you should consider before starting:
  - Regulatory strategy (drug, medical device, food supplement)
  - Indication
  - Clinical development
  - Market – claim
  - Development of the actual product
  - Reimbursement

Drug development and follow-up

Hauge og Thomassen: Legemidler og juss, Fagbokforlaget 2008



Talk with regulatory specialists

- Ask for help to set up a Target Product Profile (TPP)
- Clarify what the regulatory requirements are your product
- Do it right first time!

«Dream Product Profile»

- Indication
- Patient group
  - Age
  - Gender
  - Severity
  - Concomitant medication
- Dosing
- Duration of treatment
- Contraindications
- Precautions
- Adverse reactions

Write down your decisions

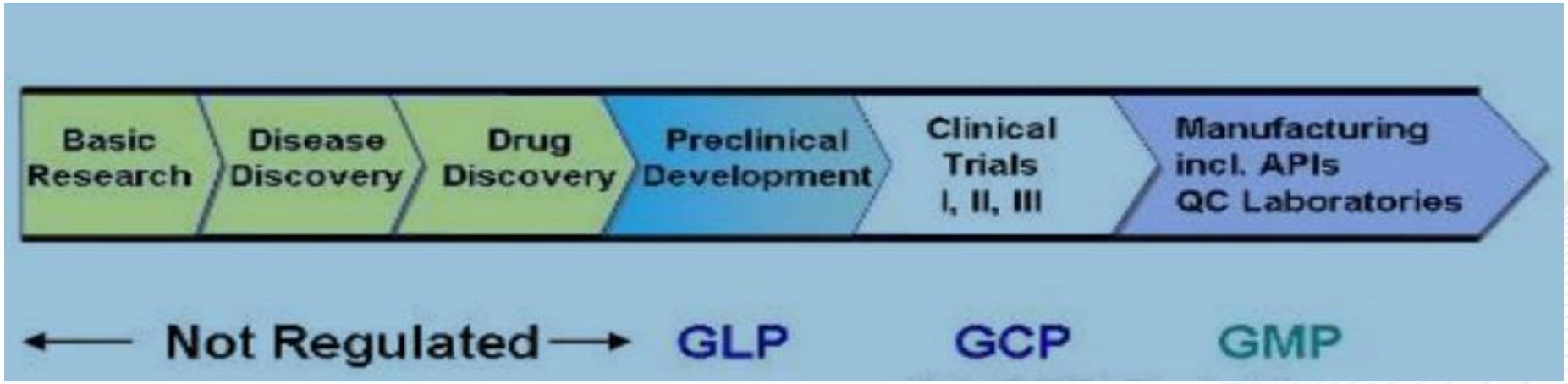
- Why do you choose this path
- What are the reasons behind your decision
- Who have you conferred with
- What inquiries have you made
- Take minutes from meetings – for your own use

Know your product

- How are you going to produce your product according to Good Manufacturing Practice (GMP)
- How will your research product differ from your final product?
- Are you able to use data from the research product?
- Impurities?
- Issues with production?
- Different producers?
- Stability – start early with stability studies – on your final product!

GxP = Principles/quality requirements ensuring compliance with legislation

- GLP Good Laboratory practice
- GCP Good Clinical practice
- GMP Good Manufacturing practice
- GDP Good Distribution Practice
- GVP Good Pharmacovigilance Practice



Transfer from idea to product development

- Can you use any of the preliminary studies for your pharmaceutical?
- GAP analysis
- Dose finding – how did you end up at your dose?
- Pharmaceutical development (galenic) – GMP
- From “research” mindset to regulatory mindset

What do you need to document

- What are the regulatory requirements for your product
  - Different requirements for different markets
  - Different requirements for different products
- How are you going to present the data – read guidelines and find suitable partners/contractors
- Make sure that you/contractor know the requirements and how your dossier must be submitted (e.g. eCTD)

Choose your vendors wisely

- What do you require from the different vendors (e.g. GxP?)
- Qualify your vendors
  - Make a checklist
  - Ask for support
- Use specialists to help you locate the best vendor for you
  - Risk evaluation
- Contracts
- Write down your decisions

Responsibilities for a Marketing Authorization Holder (MAH)

- Are you going to be the MAH – make sure you know your responsibilities
  - Pharmacovigilance - QPPV
  - QP – release of product
  - GDP – distribution
  - Product availability
  - Price
  - Reimbursement
  - Falsified Medicines Directive (FMD)
- Start preparing before you have the MA, so that you don't loose time during launch

- Product life cycle!

Take home message

- Know where you are and where you are going
- Make a plan
- Document everything
- Don’t be afraid to ask professionals for help
- Adjust your plan if necessary
- Do it right first time!

Your LINK to // optimal solutions

www.LinkMedical.eu