CDMO

Pharmaceutical manufacturer

Aseptic filling of sterile liquid and lyophilized dosage forms

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Location

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History

1999
Foundation of Baccinex SA

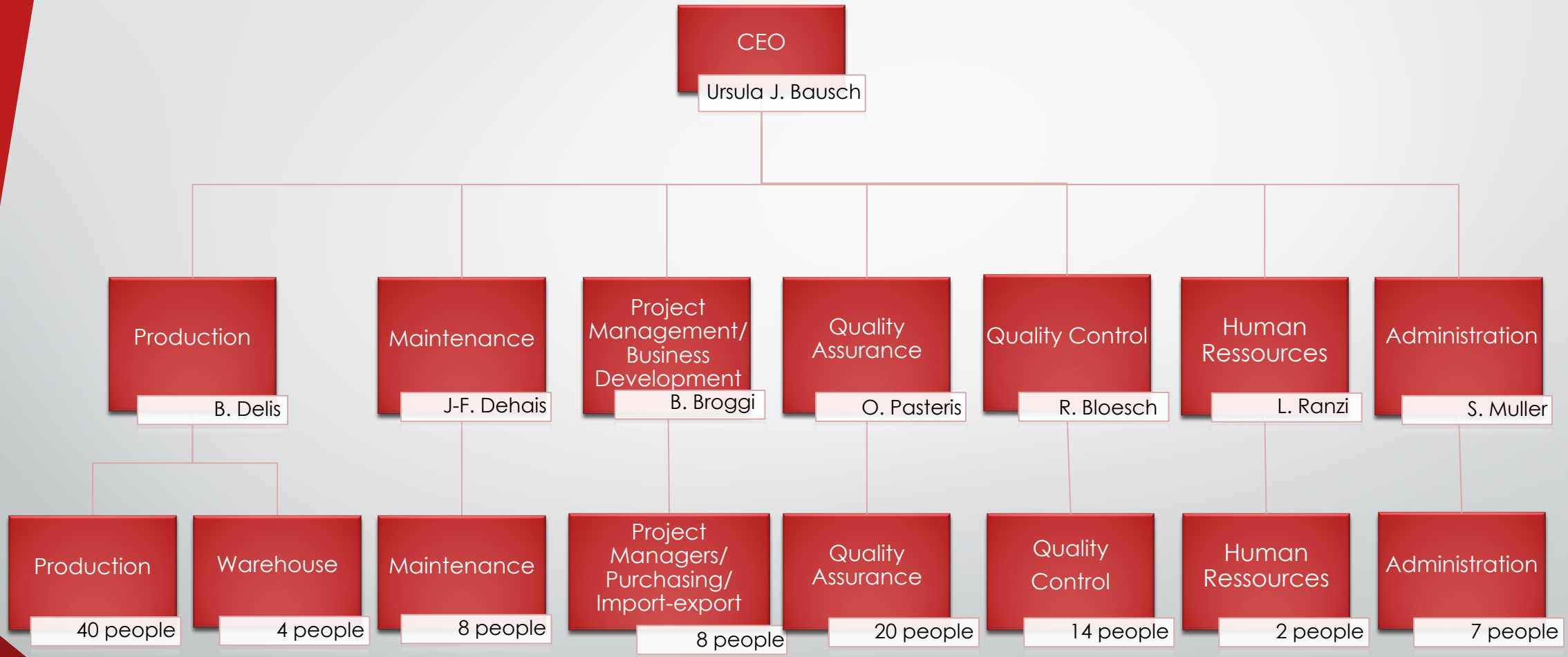
2003-2004
Installation, qualification and validation activities

2004
Certification by Swissmedic

2017
Beginning of the project of
construction of a second filling line

2021
Start of the project of building
of a new warehouse

Organisational chart



Around 120 people in total

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Mission

Production of vials for

- Clinical batches ➡ for worldwide clients (FDA agreement not required for clinical batches)
- Commercial batches ➡ for Europe
- Technical batches
  - ➡ for preclinical studies
  - ➡ for stability studies
  - ➡ for technological transfer

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Mission

One stop fill&finish partner :

- For clinical manufacturing

- For commercial manufacturing

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Mission

Client-oriented approach and specific strengths related

- Utmost flexibility related to timelines and technical solutions
- Strong project management system for a proactive follow-up of the projects
- Technical and GMP regulatory support related to the clinical project
- Extensive expertise in management of limited quantity of valuable API
- Standard MFT available
- No minimum batch size

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Strategy

Pure CDMO = Multi product facility managed by :

- Risk assessment to determine the feasibility of the project at Baccinex from a security point of view
- No handling of products requiring dedicated facilities (β-lactam antibiotics…), nor alive microorganisms
- Control of cross contamination by dedicated or disposable material

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Strategy

Multi product facility managed by :

- Standard media fill tests (covering most common worst cases) for automatic filling of vials
- Standard visual inspection qualification for operators
- Standard autoclave loads qualification (e.g.: mixed load)

Standard validated processes to be checked and accepted by clients during audit. If not in line with client regulatory understanding, specific process validation can be performed

Key figures

- 55% of clinical batches / 45% of commercial batches
- 40% of lyophilized products/60% of liquid products
- 19 years of GMP experience
- ~45 different manufacturing projects managed each year

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Development services

- Linked to scale-up and industrial transfer
  - Filter/material compatibility
  - Filter retention
- Collaboration with companies specialized in formulation and lyophilization development

Manufacturing services

- Formulation
- Aseptic compounding
- Aseptic filling of vials
- Lyophilization
- Integrity testing
- Visual inspection
- GMP Storage (15-25°C; 2-8°C; -15/-25°C; <-70°C)

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Batch sizes

Production line β

Dosage form	Liquid	Freeze-dried
VIALS		
Type	Maximum batch size	
DIN 2R	12'000	11'500
DIN 6R	6'200	6'100
DIN 10R	4'900	4'900
DIN 15R	4'900	4'900
DIN 20R	3'200	3'200
DIN 30R	2'500	2'500

Production line α*

Dosage form	Liquid	Freeze-dried
VIALS		
Type	Maximum batch size	
DIN 2R	42'000	37'000
DIN 6R	37'000	19'000
DIN 10R	33'000	16'000
DIN 15R	33'000	16'000
DIN 20R/30R	29'000	10'000

*Operational in Q2/2024

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Manufacturing services

Labelling/secondary packaging :

Activity	Labelling	Secondary packaging
Clinical batches	Customized/ randomized labelling	Customized secondary packaging such as : - Preparation of kits - Packaging for blinded clinical studies
Commercial batches	Automatic labelling	- Secondary packaging of finished products (folding boxes, leaflets) - Serialization - Tertiary packaging

Shipment

Collaboration with a qualified carrier specialized in temperature monitored shipment of pharmaceutical products

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Quality Control services

Laboratory	Activities
Physico-chimic lab	HPLC-UV (assay, purity), Spectrophotometry UV-Vis Spectrophotometry IR Sub-visible particle counting pH Water content (Karl Fischer volumetric or coulometric) Viscosity Osmolality TOC Potentiometry
Microbiological lab	Bioburden and specific germs contamination Endotoxins (turbidimetric or chromogenic technic) Sterility testing under isolator Incubation and reading of MFT at 20-25°C & 30-35°C during 7 days Environment control in classified areas

Quality Control services

- Validation of non compendial analytical methods / Suitability testing of microbiological methods :
  - Bioburden
  - Sterility
  - Endotoxins
  - HPLC etc.
- Stability study : Stability storage according to ICH conditions
  - 40°C/75%RH
  - 30°C/65%RH
  - 25°C/60%RH
  - 5°C +/-3°C
  - -20°C +/-5°C
  - Analysis according to stability program

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Quality Assurance

- Inspection by Swissmedic (Swiss regulatory authorities every 2 years)
- GMP confirmation of the batches :
  - GMP confirmation established by Baccinex' QP
  - Partnering with an European regulatory specialized company who performs EU release of batches
- Around 20 external clients' audits / year
- Quality system in place to ensure GMP compliance for any of performed activities

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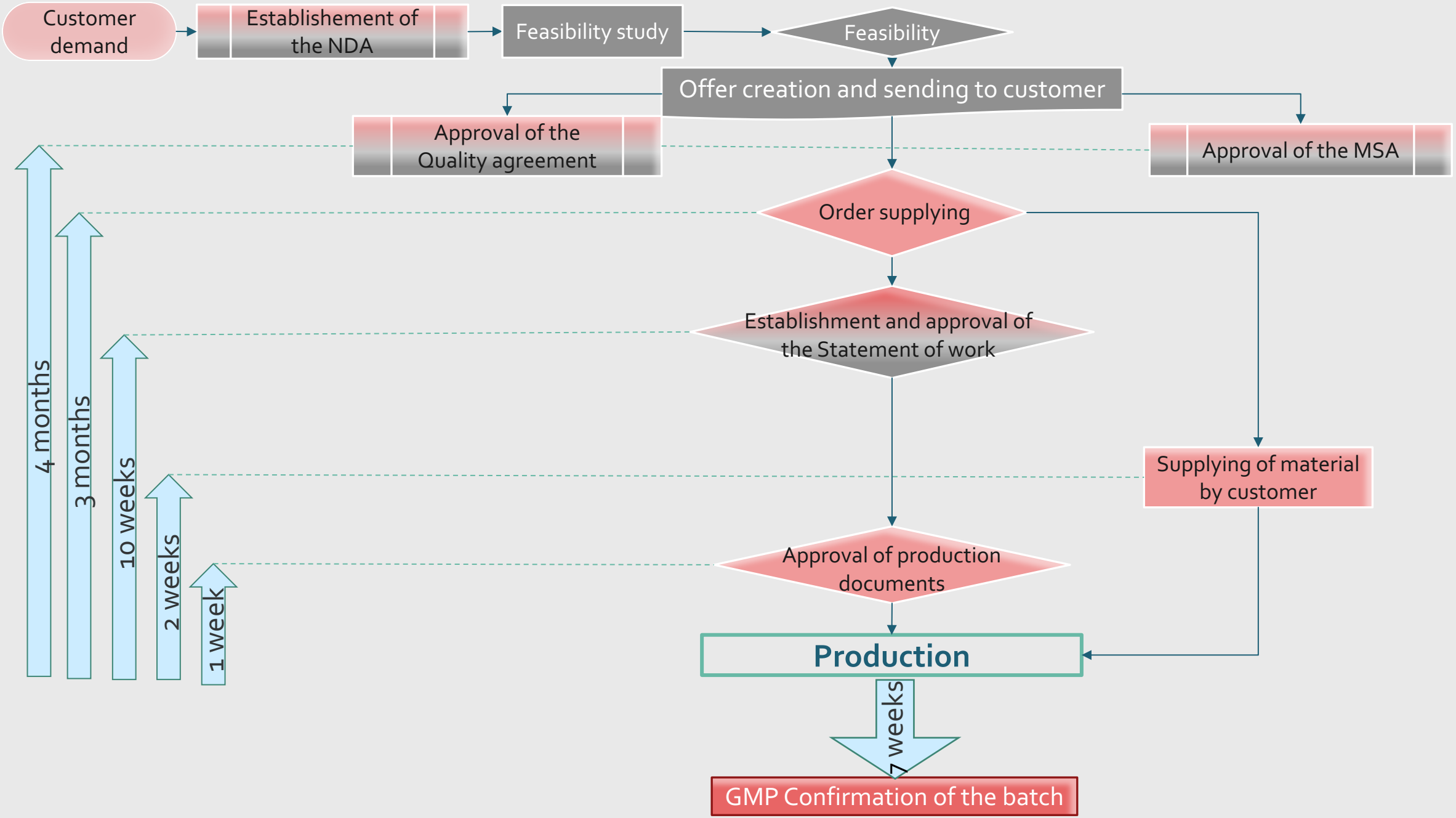
Project Management

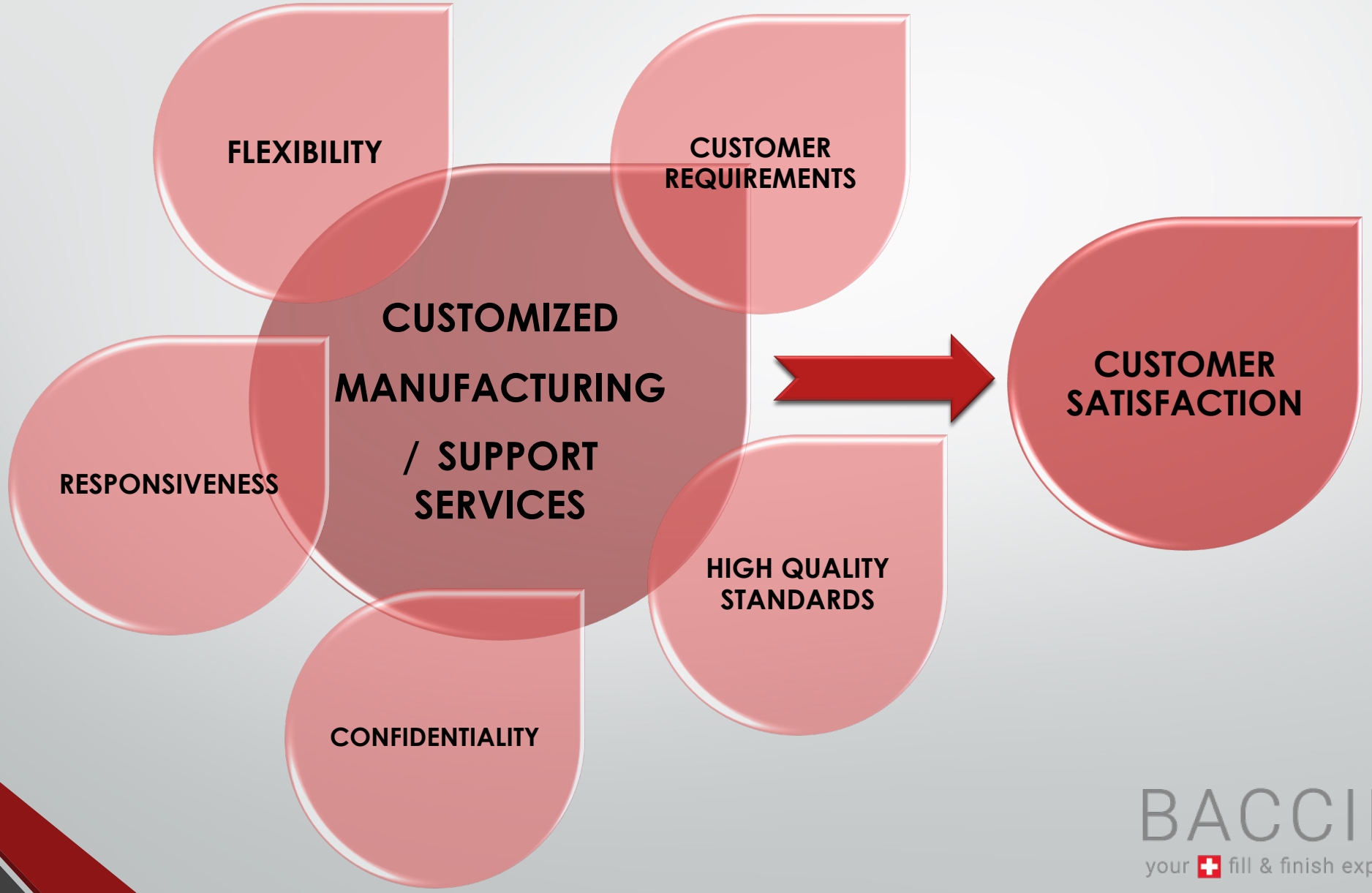
Personalized and constant support through complete project lifecycle

- Initial project assessment with client
- Proactive dedicated Project Managers as interface between client and internal project team
- Dynamic project team including the appropriate internal experts
- Specific project management tools for identifying and establishing detailed format client needs
- Recognized flexibility and strong anticipations skills on the overall project requirements
- Adaptability to project and client constraints

Milestones


Customer demand
Establishement of the NDA
Feasibility study
Feasibility
Offer creation and sending to customer
Approval of the Quality agreement
Approval of the MSA
Order supplying
Establishment and approval of the Statement of work
Supplying of material by customer
Approval of production documents
Production
7 weeks
GMP Confirmation of the batch
4 months
3 months
10 weeks
2 weeks
1 week

Conclusion



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