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CDMO

Pharmaceutical manufacturer

Aseptic filling of sterile liquid and lyophilized dosage forms

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History

- 1999: Foundation of Baccinex SA
- 2003/2004: Installation, Qualification and Validation activities
- 2004: Certification by Swissmedic / Manufacturing licence for aseptic manufacturing of sterile liquid and lyophilised dosage forms
- 2017 : Beginning of the project of construction of a second filling line

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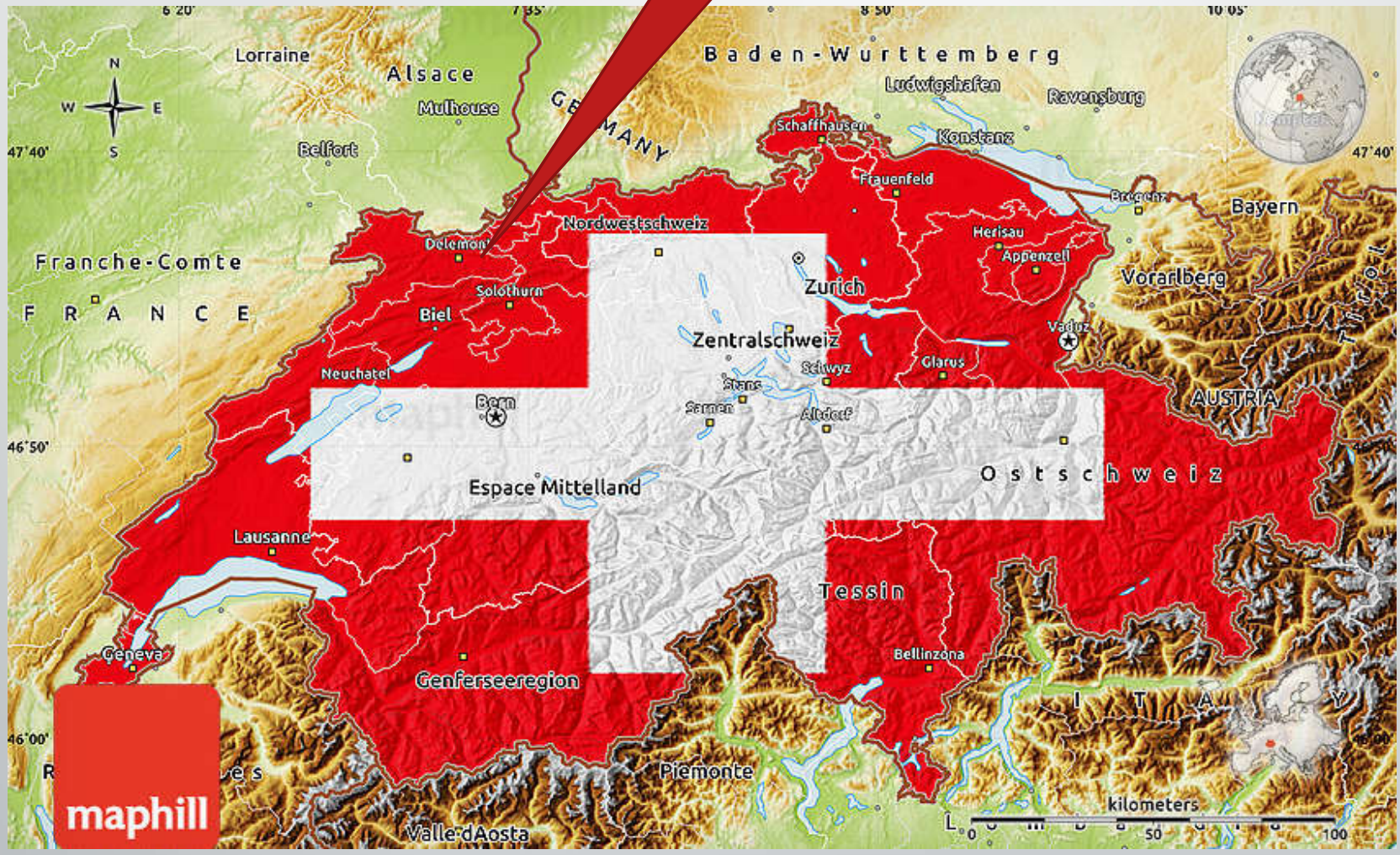
Location



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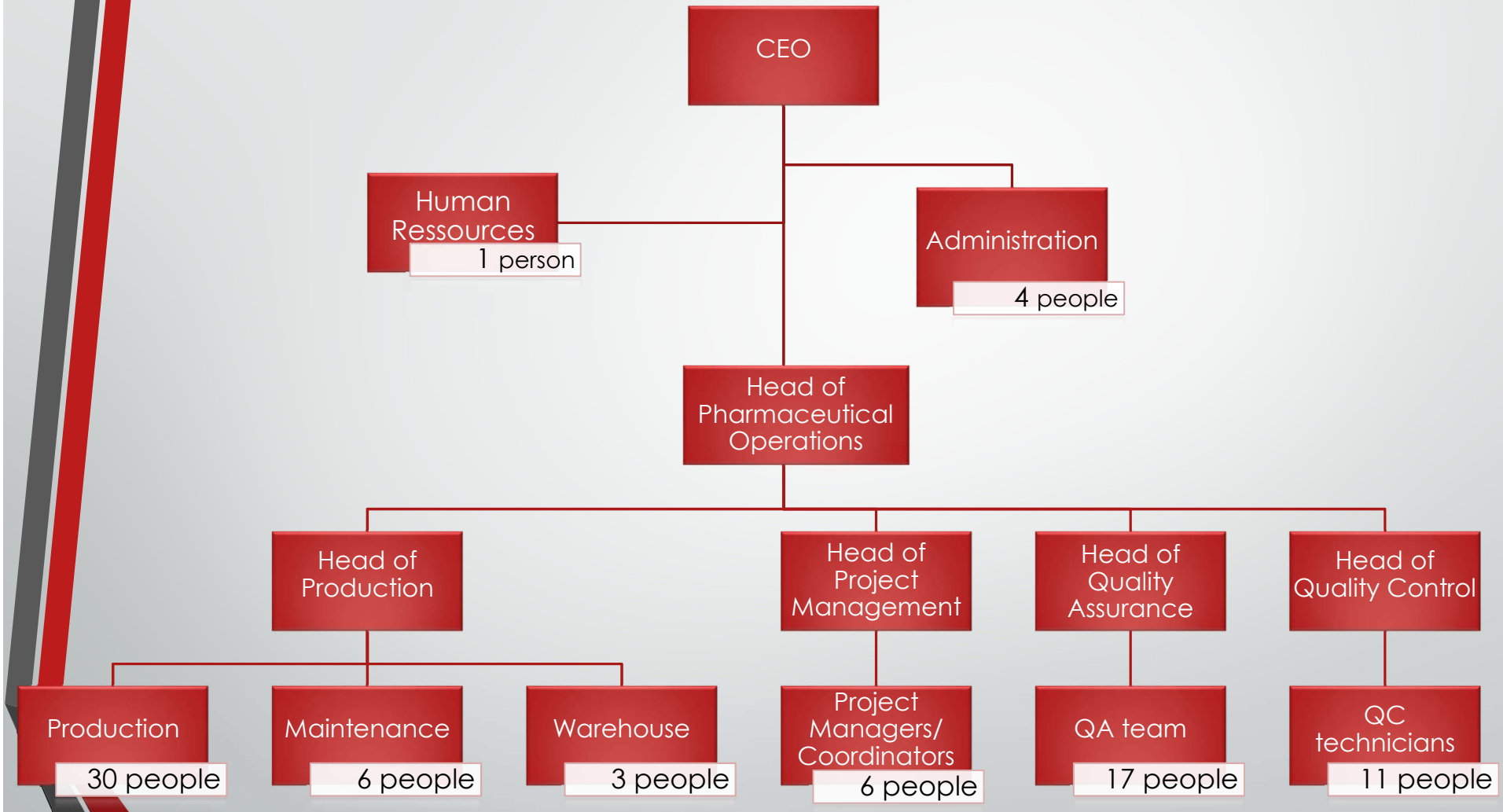
Organisational chart



Around 85 people in total

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Mission

- Production of
  - 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 contract manufacturing organization = 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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Key figures

- 70% of clinical batches / 30% of commercial batches
- 40% of lyophilized products/60% of liquid products
- Around 150 batches per year
- 16 years of GMP experience
- Around 55 different manufacturing projects managed each year

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Development services

- Freeze-drying cycle development
- Manufacturing process development and transfer
- Incomplex formulation development
- Filter/material compatibility
- Client specific development upon request

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Manufacturing services

- Formulation :
- Aseptic filling of vials and ampoules
- Sterile production by terminal sterilization
- Lyophilisation
- 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	12000	11500
DIN 6R	7000	6200
DIN 10R	6000	5000
DIN 15R	6000	5000
DIN 20R/30R	3700	3200
50 ml	2000	1250
100ml	2000	1250
	AMPOULES	
Type	Maximum batch size	
1 ml	25000	25000
2 ml	25000	25000
5 ml	25000	13500

Production line a

Dosage form	Liquid	Freeze-dried
	Vials	
Type	Maximum batch size	
DIN 2R	42000	37'206
DIN 6R	37800	19'656
DIN 10R	33600	16'380
DIN 15R	33600	16'380
DIN 20R/30R	29400	10'584

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Manufacturing services

- Labelling/secondary packaging :

	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

- Release testings :
  - Physico-chemical analysis : Main techniques for sterile liquid/lyo products, biological products
    - HPLC-UV (assay, purity),
    - Spectrophotometry UV-Vis
    - Spectrophotometry IR
    - Sub-visible particle counting
    - pH
    - Water content (Karl Fischer or coulometry)
    - Viscosity
    - Osmolality
    - TOC
    - ELISA
    - SDS-Page,
    - Thin layer chromatography
    - Potentiometry
- Microbiological analysis :
  - Sterility testing under isolator
  - Endotoxins by kinetic turbidimetry
  - Bioburden testing
  - Specific germs contamination

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Quality Control services

- Validation of non compendial analytical / 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
  - -80°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 that perform EU release of batches
- Around 20 external audits by clients/ 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

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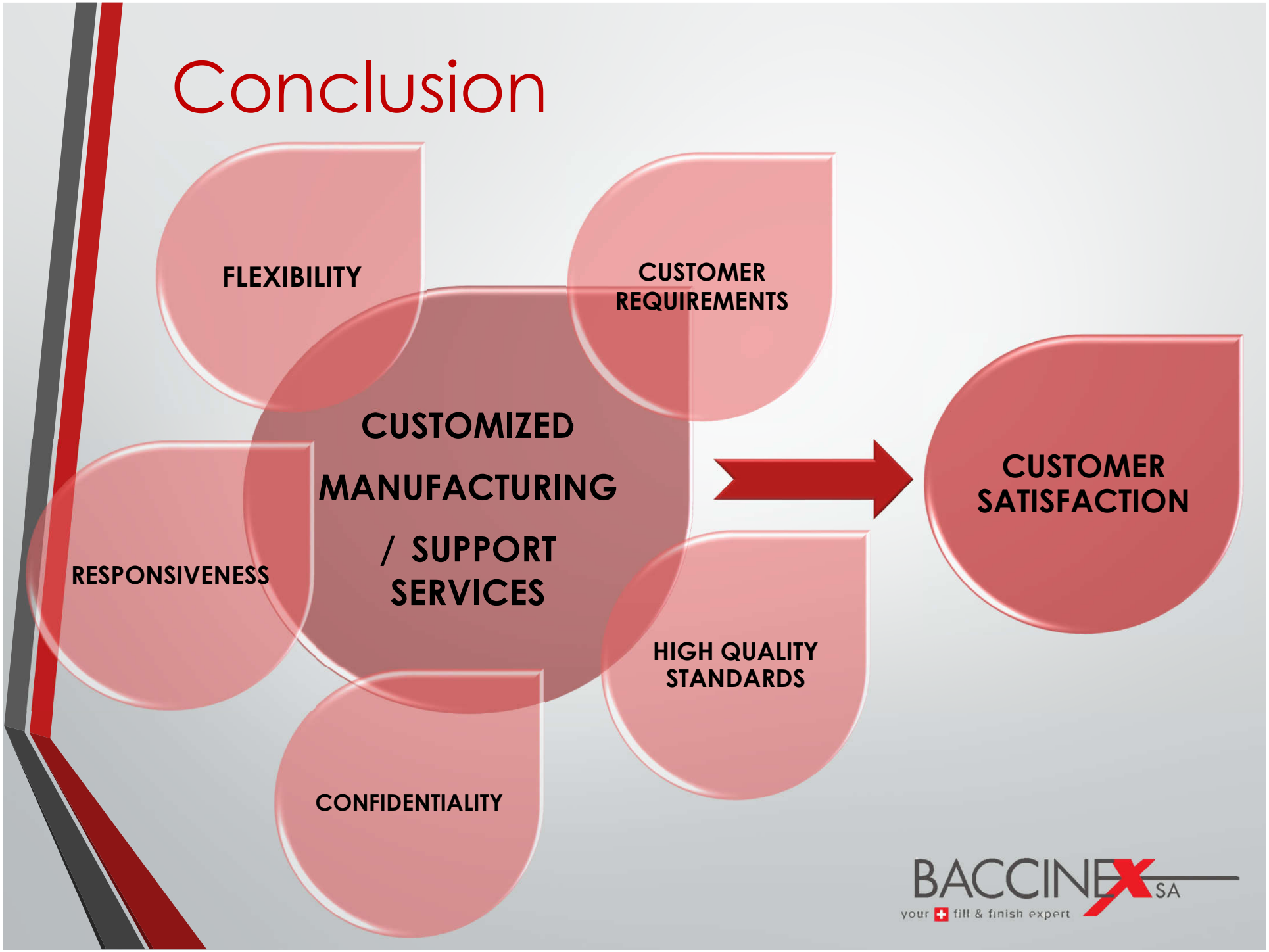
Conclusion



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