





June,23rd 2022

## io – the company

CONSULTING | PLANNING

tetragon

consulting



IMPLEMENTATION



**Production** 



Logistics





IT / SAP

#### **Project Management and Methods**

#### **Industry Expertise**

Aftersales | Automotive | Consumer Goods | Fashion

Food / Catering | Mechanical and Plant Engineering | Pharma / Biotech





### Welcome!

Tetragon Consulting Unternehmensberatung GmbH | Management Consultants since 2002



#### Growth Strategy and Organizational Development for Pharma-Technical-Operations and Pharma-Machine Engineering

"We believe that within this decade advances in pharmacy and biotechnology will make some of the world's most dangerous diseases manageable.

An important prerequisite for this is the production of high-quality medicines in the right quantity at the right time.

We advise TechOps of the pharmaceutical industry and mechanical engineering, so that this succeeds better and better.

Thus, we are proud to support the common good with our work."





### What biotech start-ups experience







#### What biotech start-ups experience

#### For me organizational development was the key issue!

- We grew from 20 to above 130 people in less than two years
- We had to recruit, on-board, align and develop teams in Business Development, CMC and Supply Chain and wanted to avoid silo thinking from the start
- A major mind-set change was required: from an agile and research driven organization to an equally process- and compliance-driven company without losing agility!

For intramuscular use. Contains no preservatives.





CTO, Biotech Start-up

### What biotech start-ups experience





We have identified eight key challenges

<b>Uncertainty</b> of pipeline success	Hiring and integrating <u>new staff</u>
Decisions have <u>long lasting impact</u>	Cultural adoptionof GMP-process- oriented attitude
	And a strength of the second strength of the
Significant resources required	Finding the right <u>CDMO-partner</u>
Vaccine	
Building up <u>new core competencies</u>	Planning an <u>own clinical samples</u> <u>facility</u>
For intramuscular use. Contains no preservatives.	









consulting Unternehmensberatung GmbH

Decisions have <u>long lasting impact</u>

> Duration from phase I until approval: ø 10.5 years

Time to set up a greenfield clinical supplies facility: > 4 years

	and the second se		1000				
	Phase Transition Durations from Phase I						
	Allergy	1.5	3.8	2.9 1	9.2		
	Metabolic	2.0	3.2	3.1	2 9.5		
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Infectious disease	2.0	3.5	3.1	1.2 9.7		
	Ophthalmology	2.1	2.9	3.4	13 9.8	Phase I to II	
Supporter with the second	Autoimmune	2.1	3.6	3.2	10.0		
	Oncology	2.7	3.7	3.1	0.8 10.3	Phase II to III	
the second second second	Respiratory	2.1	3.5	3.3	1.5 10.4		
	Psychiatry	2.3	3.4	2.8	1.8 10.4		
	Others	1.9	3.5	3.2	1.8 10.5	NDA/BLA	6
	All indications	2.3	3.6	3.3	1.3 10.5		
	Endocrine	1.8	3.4	3.7	1.8 10.	7 NDA/BLA to	
	Hematology	2.2	3.4	3.6	15 10.	Approval 7	
	Gastroenterology	1.6	3.9	3.9	14 10	8	
	Neurology	2.1	3.7	3.7	16 1	1 1	
	Cardiovascular	2.4	3.8	4.2	12	11.5	
	Urology	2.7	5.0		20 16	12.2	
	orology	4.1	5.0		2.9 1.0	12.2	
		0	3	6	9 1	2 15	
			Duration of	Phase Tra	nsition (Yea	ars)	
						15m	
Service States						1.3 1	





Significant resources required

#### **CDMO** fees

- Project management
- Cell banking
- Feasibility runs and tech transfer
- > Up- and downstream process development
- Formulation optimization
- Scale up
- Analytical method development
- Reference standard
- Dedicated equipment
- Engineering batch
- GMP batch
- Stab studies
- Process characterization



### >> 1 m€ per clinical batch

#### Investment in own facility

- Land & Building
- Clean Utilities and HVAC
- Process equipment drug substance manufacturing
- Process equipment fill/finish
- Logistics and Warehouse
- Automation and IT
- Laboratory Equipment
- Engineering services
- Qualification and validation services



#### хх to ххх m€ САРЕХ







Building up *new core competencies* 

#### CMC (Chemistry, Manufacturing, and Controls)

- Develop product formulation
- Define product characteristics and product testing
- Define and scale-up manufacturing processes
- File drug applications

# Vendor management Purchasing Supply chain & CDMO mgmt. COVID-19 Vaccine Vial contains 5 doses Vial contains 5 doses For intramuscular use Contains no preservatives 1.5m







X Hiring and integrating new staff







Ēž

<u>Cultural adoption</u> of GMP-process-oriented attitude





Finding the right <u>CDMO-partner</u>

#### Many things are important

- Technical expertise and product track record
- Experience in drug delivery systems
- > Up- and downstream process know-how
- In-house analytical capabilities

- State of the art equipment and facilities
- Laboratory space, equipment and staff
- Capacities and available slots
- Customer oriented project management

#### But most important is how the CDMO handles partnerships!

Are they good listeners?

Do they make you feel involved in the process?

When things become stressful, are they the type of company who will persevere alongside you?







Planning an own clinical samples facility

#### Things to be considered

- Product demand forecast / pipeline analysis
- Production program (>= 2 years, 3-5 years, >5 years)
- Process definition (USP/DSP & Fill/Finish)
- Primary and secondary packaging containers
- Yield expectations
- Process and change over times per batch
- Shift model analysis, process simulation
- Equipment dimensions to meet product demand forecast for drug substance (DS) and drug product (DP) manufacturing and secondary packaging (SP)
- CAPEX for land/building, HVAC/utilities, automation, production equipment, laboratory, logistics, engineering, qualification/validation
- > Time-line until commencement of production

## Unless structure follows strategy, inefficiency results.

#### Alfred D. Chandler, Jr.

#### Other options should be evaluated too

- Brownfield solution
- > Acquisition of an existing pharmaceutical plant or site
- Outsourcing production to a CDMO
- Dedicated facility at a CDMO site
- ≻ ...



We have identified eight key challenges

tetragon

consulting

Uncertainty of pipeline success	Hiring and integrating <u>new staff</u>
Decisions have <u>long lasting impact</u>	<b>Cultural adoption</b> of GMP-process- oriented attitude
	And a strength of the second strength
Significant resources required	Finding the right <u>CDMO-partner</u>
Vaccine	
Building up <u>new core competencies</u> ses	Planning an <u>own clinical samples</u> <u>facility</u>
Contains no preservatives.	



Mentimeter survey – What are your top key challenges?





IO and Tetragon provide a holistic approach





## We appreciate your feedback; please contact us any time!





#### **Tim Walter**

Business Unit Manager io-consultants GmbH & Co. KG

Phone: +49 6221 379-261 Mail: Tim.Walter@io-consultants.com



#### Morten Schlothauer

Managing Director Tetragon Consulting Unternehmensberatung GmbH

Phone: +49 6151 50118 50 Mail: m.schlothauer@tetragon-consulting.com



