Project Type: Pharmaceutical manufacturing facility project

Project Name: HMO KAL
Risk Register

For Input

Do not Change / Automatically calculated cell

Identification						Impact Assesment												Response Planning and Progress
Col. 1	Col. 5	Col. 7	Col. 8			Col. 9	Col. 11	Col. 12	Col. 13	123 362 000	Col. 15					#NAME?	#NAME?	Col. 18
Risk No.	Process Area - Work Package/Lot	Risk Headline	RISK Description What can go wrong? Why can it go wrong? State the effect and area/s affected. Where and How?	Category (Risk, Issue/Challenge)	Grading 1->5 1 is the lowest in importance	Severity of the RISK's Impact (drop-down list)	Cost of Risk (€)	Likelihood of Ocurrence (drop-down list)	Likelihood Factor 1 ---> 5	Cost x Likelihood (%) (€)	Level of Risk	Likelyhood Sim 1	Likelyhood Sim 2	Sim 1 Occurs?	Sim 2 Occurs?	Cost 1	Cost 2	MITIGATION Preventive Measures / Actions / Controlability (Insert a detailed Description)
1	**Automation**	Lack of skilled programmers for the chosen Automation System (ABB 800xA DCS System)	Risk: Onboarding of qualified ressources (Project). We are also lacking resources at the managerial level. Closed and linked to Risk 46	Issue		**Severe**	**10 000 000**	**High**	4	7 000 000	20	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	
2	**PM-OPS**	Onboarding of qualified ressources (Process)	We can´t find the right competencies due to heated market - engineers, technician and operators in the area because the competition is high in the Kalundborg area.	Issue	**1**	**Moderate**	1 250 000	**Medium**	**3**	500 000	**9**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**Design an strategy to retain and atract talent, where salary is not the only incentive. Make a list of the most critical skills/experience that we are missing and when do we need them, then assess if an early recrutiment is needed. Early engament in developemnet a working force for the future.**
3	**PM-ENG**	Lead time components for plant construction	Lead time on equipment and components are higher than we plan for. If it happens it will affect our time objective and perhaps our cost as well.	Risk	**5**	**Major**	3 500 000	**High**	**4**	2 450 000	**16**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**Develop a Proactive plan of action and communication with suppliers and contractors.**
4	**Demolision (Desmantling)**	Building damage	Major building damage during demolishing, adding substantial time to reconstruction of building etc Damage to actual building.	Risk	**1**	**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**Need to analyze how probable this is How much are we saving by trying to keep the existing buildings and compare to alternatives.**
5	**PM-ENG**	Undefined project objectives.	For now it is undefined when the project ends. - When the factory is ready for production? - When the factory has been running x batches - When the factory has been running for x mont. Defenition of objective supon delivery. When is the project executed.	Issue	**2**	**Moderate**	1 250 000	**High**	**4**	875 000	**12**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**To develop a clear success criteria/objectives**
6	**Automation**	Wrong functionality of the process	Unclear process description towards to automation. Lack of communication	Issue	**1**	**Moderate**	1 250 000	**Medium**	**3**	500 000	**9**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**Facilitate the connection/communication between process and automation.**
7	**PM-ENG**	Interfaces	Insufficient description of responsibilites and interfaces in contracts. Results is bad contracts and a lot of extra coordination(responsibility) by Chr. Hansen	Risk	**5**	**Major**	3 500 000	**High**	**4**	2 450 000	**16**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**Allow enough time, within the time limitations of the project, to describe the interphases. Identify the most critical interphases. Choose the right tender strategy.**
8	**PM-ENG**	Insufficient time create time pressure to make decisions on shaky input	Risk: neglecting the need for more time and rushing to present something to the board that lacks validity or still has a big variance. Effect of a risk: Deliverables will not meet the expected quality. Due to time pressure, modification made to the design might not be fully evaluated and result in unwanted consequences which either hinder the quality of the result, or require additional time/cost to fix.	Risk/ effect of a risk	**5**	**Major**	3 500 000	**High**	**4**	2 450 000	**16**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**Present with transparency, and/or partially accept this risk if we want to move in with part of the project, while we develop a better CD or BD for the overall.**
9	**Quality**	Sub-standard Qualification/testing	Details in qualification level not clear and/or testing does not uncover severe equipment and process issues	issue	**2**	**Major**	3 500 000	**Medium**	**3**	1 400 000	**12**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**Partial mitigation strategy: To develop and communicate the success criteria after CD is delivered from NIRAS.**
10	**PM-ENG**	Expectation misalignment	Deliverables will not meet the expected quality due to time pressure. + Missing communication lines going towards next fase. Incl. descision tree.	Issue/Risk	**5**	**Major**	3 500 000	**High**	**4**	2 450 000	**16**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**NIRAS and Chr. Hanssen relationship should be well defined as a partner not as just a supplier.** **+ Develop an organizational diagram for the project where the decison process is clear (in and out of the project)** **+ Develop a work breakdown structure that can lead to a solid schedule and conduct a thorough analysis in terms of criticality - critical path**
11	**Process**	How to prove URS requirements	Unclear URS' , resulting in impact on project deadlines.	Issue	**1**	**Major**	3 500 000	**Medium**	**3**	1 400 000	**12**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**To make sure the process is carried out, is normal procedure.**

12	**PM-ENG**	Missing communication lines going towards next fase. Incl. descision tree.	Information don´t reach the correct recipient Project participants don´t know how and to who to communicate. Link to n. 10	issue		Moderate	1 250 000	High	4	875 000	12	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	
13	**PM-ENG**	Lack of planning	1. Do not meet deadlines. 2. No allignment and planning. 1. We need to identify what might happen that will result in the project been delayed. Depending on Niras delivery. Once we get NIRAS we need to develop our own plan. This is also link to n. 10	1. effect of risk. 2.issue		Major	3 500 000	High	4	2 450 000	16	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	
14	**PM-ENG**	CD not completed before BD.	Give a wrong decision base to CH board CD deliverables not finalized before deadline.	Risk	**2**	**Major**	3 500 000	**Medium**	**3**	1 400 000	**12**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**Clarity and transparency to the board. To let them know where are we in project and the level of variance or risk.**
15	**PM**	Experience with project execution of large projects	Missing internal experience on project size.	Issue	**2**	**Major**	3 500 000	**High**	**4**	2 450 000	**16**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**Make a list of the most critical skills/experience that we are missing and when in the processs are those skills/ resources needed. (See if we can find some of those skills or expertise within CHR HANSEN)**
16	**PM**	Repeat previous projects errors.	We don't learn from other projects. Plan to spread information aout past projects, conducting risk sessions.	issue	**2**	**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**Share more experiences from within the organization, create a sharing space, meeitng or brainstorming and bring a guest speaker from other projects to provide with example cases to learn from others. We can also bring cases from outside CHR HANSEN.**
17	**PM-OPS**	New Organization	We are a lot of new employees in Kalundborg and we do not necessarily (have) the network in Chr. Hansen. Kalundborg organization feels isolated.	issue	**2**	**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**Implement a plan of integration an communication channels.**
18	**PMG**	DSP Process define	We do not have enough data to decide the best technology for especially primary separation but also to scale up the unit operation used today. Issue for the process workstream. We risk to establish wrong process and/or not the capacity we need. Closed: covered by ID32	Risk	**4**	**Moderate**	1 250 000	**High**	**4**	875 000	**12**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**This needs to be more detailed and separated into the different sub-processes. Then stablish an individual mtigation action**
19	**Management**	Market	Lack of knownledge about the business case can cause bad descision making. Too expensive solutions effects the cost of the final product.	issue		Major	3 500 000	Medium	3	1 400 000	12	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	
20	**PM-ENG**	Time	We are later to maket than estimated (2024) due to delays during construction. It will impact the business plan.	effect of a risk. Business risk. Not project risk.	**2**	**Moderate**	1 250 000	**Very High**	**5**	1 125 000	**15**	**90%**	**50%**	#NAME?	#NAME?	#NAME?	#NAME?	**We need to identify what might happen that will result in the project been delayed. Look at it again after CD is finalized.**
21	**EHS**	Authority	Unknown authority requirements. Handling of GMO becomes very expensive due to requirements from the authorities. Affects the price of the final product. Check probability and impact	risk	**2**	**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**When can we have more certainty about the requirements?**
22	**PM-OPS**	Core competences leaving the project	If employees with core competances leave the project we will loss important knowledge (and time) that we cannot necessary replace. It can go wrong if people is moved to other projects or if employees are leaving chr. Hansen	Risk, unless it is happenig then it is an issue and we need to act.	**4**	**Major**	3 500 000	**Medium**	**3**	1 400 000	**12**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**Develop a Proactive plan of action and communication with the team. Constant and open channel of communication, will help build a stronger and cohesive organization. Establish a better communitacion plan about the project derivables to obtain better alignment.**
23		Authority	The review proces of GMO by the authorities will last a lot longer than expected due to resistance to antibiotics. Delays the design and construction, and ultimately the production date.	Risk. The risk is closed because the antiobiotics that are resistance markers will be remove before starting production in KAL		Moderate	1 250 000	Low	2	225 000	6	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	
24	**PM-ENG**	Underestimate project size and complexity + Missing communication lines going towards next fase. Incl. descision tree + Lack of planning	CH project not able to specify requirements CH project organization too small. Project participants don´t know their own role + Information don´t reach the correct recipient Project participants don´t know how and to who to communicate +Effect of risk: We do not meet deadlines. Issue: No allignment and planning		**4**	**Major**	3 500 000	**High**	**4**	2 450 000	**16**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**Develop a detailed org. diagram with clear roles/responsibilities + channels and modes of communication.**
25	**PM-OPS**	Waste	The biomass-fraction from fermentation can only be delivered to one vendor, thus making us very dependent on this collaboration. Will cause the production to stop if the biomass is not collected due to limited storage capacity on site.	Risk (Operational)	**1**	**Major**	3 500 000	**Low**	**2**	630 000	**8**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**How certain is this? If it is factual then we are looking at an issue. If not we need to analyze probability. Look at volumes, and possibility to storage biomass until it is collected.**
26	**EHS**	Sustainability	We must to some extent be sustainable, but we do not know the level and the cost associated. Many factors influeces the level, and therefore it has great uncertainty. If the site is not sustainable it has a cost, either/both direct or/and indirect.	issue/risk..	**1**	**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**Risk only if we dont comply with the required authorities standards. .. Need to understand better our sustainability agend**
27	**PM-ENG**	Stakeholder	The project team does not know the expectations by the board, and therefore the CD work and CAPEX budget will not meet the expectations and level of detail. The project is delayed and will cost more. 56 is linked.	Issue	**3**	**Major**	3 500 000	**Medium**	**3**	1 400 000	**12**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**Communication strategy with the team. Highlight the final goal of the CD.**

28	**Automation**	Automation	The automation system is not robust enough, causing downtime and in worst case a fermentation that goes wrong and must be discarded. Dependencies on subcontractors/vendors and internal ressources is a weak link, that influences robustness. The concern is the robustness of the system.	Issue (Operational)	**3**	**Major**	3 500 000	**Low**	**2**	630 000	**8**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**Define how robust it should be. How do we get the required robustness, contact the right suppliers.**
29	**Building**	Not enough land	We do not have enough land. It can go wrong because we do not have the size of the buildings.	Issue	**4**	**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**Needs to be evaluated and determine with precison how much land do we need and have, before moving forward or during basic desig.**
30	**PM-ENG**	Time	Lack of an overall time schedule leads to uneven prioritisation in the workstreams and the overall project. Leads to different maturity and bad coordination of interfaces. Delays the CD and thus the overall project	Issue	**3**	**Moderate**	1 250 000	**High**	**4**	875 000	**12**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**We now have an improved timescheule in place to follow up together with NIRAS**
31	**Building**	Soil works	Uncertainty: Soil works are more comprehensive than expected due to polution, water level etc. Possible effect: Adds extra cost and time to the construction. Delays the production date. Check probability and impact	Risk	**4**	**Moderate**	1 250 000	**Medium**	**3**	500 000	**9**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**We have to wait to know where excavation will take place. Talks with Niras are in placed. Estimating of a 1m eur max**
32	**PM-OPS**	Downstream	Part of the downstream proces can not be scaled up compared to RBB. We therefore don't have a tested and documented basis for every step in the downstream, thus making the project partly RD. Causes the downstream to malfunction.	Issue. the fact is that we can't scale it up. This is happenning, how do we move forward? inability to testing has been already communicated to SCO.	**4**	**Severe**	10 000 000	**Medium**	**3**	4 000 000	**15**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**Early engagement with suppliers and between DK and DE sites where allowed.**
33	**PM-ENG**	Scope	Lack of communication of overall succes criterias give the wrong prioritisation and descision making in the work streams, and work of the consultant is not of high value. In worst case it halts the project since the next phase can not be approved by the board. linked to risk 32	issue. Mitigation to develop a clear success criteria		Moderate	1 250 000	High	4	875 000	12	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	
34	**PM-OPS**	Lack of time schedule	RBB closes by the end of 2024. We don't have downstream capacity anywhere, not even with CMOs. Downstream is therefore the most important part of the process. Lack of overall time schedueling leads to wrong prioritisation and in worst case an unfinshed downstream in time (effect)	Issue RBB closing this is a fact. It is certain and it is not a problem unless we cant start producing by 2024. then we could analyize if there is uncertainty linked to that objective. Not knowing the time schedule will as a result delay the project (effect of a risk)	**4**	**Severe**	10 000 000	**Very Low**	**1**	500 000	**5**	**5%**	**1%**	#NAME?	#NAME?	#NAME?	#NAME?	**Allocate a time buffer and stock-up before closing RBB. Stablish amoutn of time and quantity.**
35	**PM-ENG**	Overall success criterias	Lack of communication and focus on the overall succes criterias means that e.g. modularity is not incorporated sufficiently in the design and layout. + give the wrong prioritisation and descision making in the work streams, and work of the consultant is not of high value. Phase 2 can not be completed at a low cost and in time to meet market demand. In worst case it halts the project since the next phase can not be approved by the board.	Issue	**4**	**Major**	3 500 000	**Medium**	**3**	1 400 000	**12**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**To develop a clear success criteria/objectives**
36		Objectives we do not hit our target infividually as team	Project delayed (effect) facility not designed correct (Effect) Closed and linked to 35	effect of a risk.		Major	3 500 000	High	4	2 450 000	16	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	
37		Objectives quality level of CD deliverables not defined	The CD will not have the right scope. The price estimate will be wrong. Decisions made on wrong basis. Closed and linked to 35	effect of a risk.		Major	3 500 000	Very High	5	3 150 000	20	**90%**	**50%**	#NAME?	#NAME?	#NAME?	#NAME?	
38		Objectives unclear definition and control of scope	The CD will not have the right scope. The price estimate will be wrong. Decisions made on wrong basis. Closed and linked to 35	effect of a risk.		Moderate	1 250 000	Medium	3	500 000	9	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	
39	**PM-ENG**	The process group deliver not the right level of quality or wrong. Closed: covered by ID75	As the level of detail is not defined it is hard to know what level to hit	Issue	**3**	**Major**	3 500 000	**High**	**4**	2 450 000	**16**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**To develop and communicate the success criteria after CD is delivered from NIRAS.**
40	**PM-ENG**	Unclear/changing definition of objectives due to business uncertainty,	The facility will not suit the needs when it is up and running	Effect of a risk	**3**	**Moderate**	1 250 000	**Medium**	**3**	500 000	**9**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**To develop and communicate the success criteria after CD is delivered from NIRAS.**
41	**PM-ENG**	Scope of the factory/phases not defined (too much or too little flexibility)	The CD will not have the right scope. The price estimate will be wrong. Decisions made on wrong basis	Effect of a risk	**3**	**Major**	3 500 000	**Medium**	**3**	1 400 000	**12**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**To develop and communicate the success criteria after CD is delivered from NIRAS.**

42	**PM-ENG**	Too optimistic time schedule	Lack of experience and time to complete the task leads to a far too optimistic time schedule for the coming phases and construction. Decision making to continue on a wrong basis.	Issue/risk	**4**	**Major**	3 500 000	**Medium**	**3**	1 400 000	**12**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**Develop a thorough work breakdown structure that wil help us identify the critical path and the interphases to look at.** **+ Involve experienced external parties to review our timeschedule.**
43	**PM-ENG**	Too optimistic CAPEX budget	Lack of experience and time to complete the task leads to a far to optimistic CAPEX budget. Decision making to continue on a wrong basis. Impacts the final price of the product.	Issue/risk	**4**	**Major**	3 500 000	**Medium**	**3**	1 400 000	**12**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**Develop a thorough work breakdown structure that can evolve into a solid cost break down structure** **+ Involve experienced external parties to review our timeschedule. KOSMOS currently revising the Building and utilities package.** **Find other experienced external parties to assist.**
44	**PMG**	No time/ capability to do experiments to support design and scale up	We built too much or too little capacity or too much flexibility.	Issue . See risk 32. This is happenning, how do we move inability to testing has been already communicated to SCO.	**4**	**Moderate**	1 250 000	**Medium**	**3**	500 000	**9**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**Early engagement with suppliers and between DK and DE sites where allowed.**
45	**PMG**	Process uncertainty. design based on a lot of assumption, no documentation of existing process (not commectially viable). Lack of tech transfer documentation from RBB	The factory will not work as intented if assumptions does not hold.	Issue. This is happenning, how do we move inability to testing has been already communicated to SCO.	**4**	**Severe**	10 000 000	**Very High**	**5**	9 000 000	**25**	**90%**	**50%**	#NAME?	#NAME?	#NAME?	#NAME?	**This is happenning, how do we move froward?** **Early engagement with suppliers and between DK and DE sites where allowed.** **inability to test has been already communicated to SCO.**
46	**PM-ENG**	Lack of resource availability (internally and externally) for a project of this size due to market conditions. (operators, engineering, contractors).	Project can be delayed. Deliverables will not meet the expected quality. The risk of lower quality will cause a project delayed, how can we prevent this, Similar to risk 1 and 2. Automation: Lack of skilled programmers for the chosen Automation System (ABB 800xA DCS System)	Issue. We need to act on it.	**3**	**Major**	3 500 000	**High**	**4**	2 450 000	**16**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**Design an strategy to retain and atract talent, where salary is not the only incentive. Important to highlight why we need this resources. Need to build a case to show the benefits of in-house resources (for some resources) . When hiring external make sure the lenght of the job, person and capabilitites are well defined in the contract, to avoid gettign a resources woth lesss capabilities or experienced than required, specially in cases where the external stops and a replacement is sent.**
47		Resources "Kalundborg factor". Dificult to attract and maintain staff. High competition from NN and NZ	It might be difficult or more expensive than expected to staff the project and the production facility. Closed and continue on risk 1 and 2.	Issue		Major	3 500 000	Medium	3	1 400 000	12	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	
48	**PMG**	Major upscaling	The process units will not have the correct size and the line will result in having too low capacity, need to be corrected resulting in higher CAPEX . Risk of having the wrong design.	a risk we might have to take/accept. However we need to find ways of minimize it. See risk 24. This is happenning, how do we move inability to testing has been already communicated to SCO.	**4**	**Severe**	10 000 000	**High**	**4**	7 000 000	**20**	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	**Early engagement with suppliers and between DK and DE sites where allowed.**
49		Resources This type of facility is new to Chr. HAnsen and Niras	We do not have the right competences required to design and build such a facility. Closed an linked to risk 46.	issue. The process of starting a factory is not new to any of the two, neither is the production. We are looking, internally and exteranlly, for the resources we lack.		Moderate	1 250 000	Medium	3	500 000	9	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	
50	**PM-ENG/PM-OPS**	Process uncertainty. Design definition takes too long.	Affect timeline and delivery of factory. Effect of risk. What is the risk? Process uncerainty. Closed and linked to 35	effect of a risk		Moderate	1 250 000	High	4	875 000	12	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	
51		Time schedules CD not finished on time at right quality.	The price estimate might be wrong. Decisions made on wrong basis. Closed and linked to 39	issue		Moderate	1 250 000	High	4	875 000	12	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	
52		Time schedules start new phase before being ready	Deliverables will not meet the expected quality. Closed and linked to 39	effect of a risk		Major	3 500 000	High	4	2 450 000	16	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	
53	**PM-OPS**	RBB resources	Insufficient RBB resources support production and project will cause deliverables do not meet the expected quality	Risk	**4**	**Moderate**	1 250 000	**Medium**	**3**	500 000	**9**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**We need to get the know-how whether sending dk resources to germany or bringing them here. At this stage it is better to send DK to GE. Key process people onboarded on time. To create some sort Resource break down structure to identify critical resources and when to onboard them.**
54	**PM-ENG**	Phased implementation adds complexity	When deciding to phase the implementation, consequences of delaying part of the construction might not be fully understood, resulting in non completely functional first step, or considerably more expensive second step.Second step will have to be implemented shortly after first one, making it potentially for 2 parallel projects (the first one close to completion, the second one at early stages). The second part of the implementation will have to happen in a producing facility.	Risk/fact.	**3**	**Moderate**	1 250 000	**Medium**	**3**	500 000	**9**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**The plan of action needs to be better defined (it is in process) and then decide up to what level of risk we as an organization are willing to take. - Definition of bottle neck phases, stages or final capacity goals and caps need to be defined prior to starting the first execution phase.**
55	**PM-ENG**	Delays in external procedures/contractors (power, permitting).	It might take longer than planned to secure all external precondition to the project (permitting, demolition, contractors availability). Project will be delayed Closed: covered by other more specific risks	Risk	**3**	**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**This type of permits and procedures are being dealt with already- it is important to stablish a proactive approach and account for realistic roadbumps= delays or extra costs- Include permiting as milestones or processes in the time line.**
56	**Quality**	Current product requirements and quality level might not be representative of future market (over under design) or future products.	The built facility will not live up to the customer requirement and must be modified. Increase in CAPEX. The risk is partially adressed in risk 49- Food quality vs Pharma quality - **Business risk.**	effect of a risk	**1**	**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**Food quality vs Pharma quality - Business risk.**
57		Communication/ Alignment Level of certainty/proof required with respect to process, design etc.. (does everything need to be tested, or do we build and fix?).	We need to take a descision to make sure everyone is on the same page. This is closed and linked to risk 27	Communication issue. Communication strategy with the team.		Moderate	1 250 000	High	4	875 000	12	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	
58		Communication/ Alignment engineering partner deliver something not aligned with expectation	Deliverables will not meet the expected quality. Project will be delayed. Closed and linked to Risk 39	effect of a risk		Major	3 500 000	High	4	2 450 000	16	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	
59		Communication/ Alignment Project execution not carried out in the correct way or aligned with our expectation, quality suffers.	Deliverables will not meet the expected quality. Project will be delayed. Closed and linked to Risk 39	effect of a risk		Major	3 500 000	High	4	2 450 000	16	**70%**	**37%**	#NAME?	#NAME?	#NAME?	#NAME?	
60	**EHS**	VVM approval	Approvals from the Environmental Protection Agency takes longer time than expected	Risk	3	**Major**	3 500 000	**Low**	**2**	630 000	**8**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**Investigate whether an EIA screening (VVM) is sufficient, or an EIA examination must be performed**

61	PM-ENG	Covid-19 inflation	General price increase due to the Covid-19 pandemic results in higher CAPEX prices	Risk	4	Major	3 500 000	Very High	5	3 150 000	20	90%	50%	#NAME?	#NAME?	#NAME?	#NAME?	Accept and include risk for price increase in CAPEX estimate based on successive calculation.
62	Utility	Delayed power supply	Cerius has informed that is takes 2 year after Chr. Hansen has signed a contract before they can have established additional power to site	Risk	3	Moderate	1 250 000	Low	2	225 000	6	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	Accept and handle as a long lead item Strive to get the 50/10 kV station on site Ongoing dialogue with Nexel (Cerius) and other stakeholders in Kalundborg
63	Building	Insufficient site area	Layout space requirements are greater than assumed to be able to handle process, 50/10 kV station and future extensions	Issue	5	Moderate	1 250 000	High	4	875 000	12	70%	37%	#NAME?	#NAME?	#NAME?	#NAME?	Evaluate possibilities to purchase of additional land (10.000 m2)
64	PM-ENG	Increased cost from EV to CD	Higher expectations and requirements are set than were estimated in the Evaluation Study/Costs of expectations and requirements set in the Evaluation Study were not fully included	Issue	4	Moderate	1 250 000	Very High	5	1 125 000	15	90%	50%	#NAME?	#NAME?	#NAME?	#NAME?	Savings catalogue and workshop Value engineering
65	PMG	Freedom to operate	FTO (freedom to operate) is not secured with the process changes planned	Risk	4	Severe	10 000 000	Low	2	1 800 000	10	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	Secure FTO (freedom to operate) and ensure that patents are not violated with the process changes planned in the project.
66	EHS	Increased injury frequency as a result of tight contract deadlines (especially civil works, but also e.g. installation of equipment)	It's a known phenomoma especially in the construction industry contracts with very tight deadlines can lead to an increased frequency of work related injuries. Also, contracts not focussing on enforcing a zero work injury culture, but solely focussing on time and cost as performance	Risk/ increased TRIF/LTI frequency in project		Major	3 500 000	Low	2	630 000	8	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	Include EHS metrics in all contracts - AND make realistic contractual agreements with suppliers which are possible to achieve while maintaining a safe work culture.
67	Utility	District Cooling	District cooling is being evaluated as an alternative to cooling towers. Novo Nordic is the main driver of the project and has a deadline for GO/NO-GO 31st Maj 2022. Which solution is to be included in BD and what is the impact of a wrong decision	Issue /Risk		Moderate	1 250 000	Medium	3	500 000	7	40%	17%	#NAME?	#NAME?	#NAME?	#NAME?	The BD is not finished, but will have to be up-dated for the technical solution in utility building. This will have an impact of the design of the utility building incl loads
68	Utility	District Steam	Steam supply is in CD2.0 based on that an agreement is made with Ørsted of supplying district steam to the site to cover base load.	A risk we might have to take/accept.		Minor	300 000	Low	2	54 000	4	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	A fourth boiler will have to be installed alternatively a bigger third boiler
69	Utility	Existing utilities	The existing utility plants in building J can not be restarted due to problems of not have being in use for 5 years or more	Risk of delayed start		Severe	10 000 000	Low	2	1 800 000	25	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	Evaluate if this risk is real. Continue auditing the existing plants and hire somebody to start-up the equipment where audit does not minimise the risk/give a clear indication of what the equipment can be put in operation. Investigate if units can be leased to cover for the missing capacity. When is the deadline for the decision?
70	Utility	Chloride in waste water	Chr. Hansen will not be given an exemption for a Chloride content in waste water > 1000 ppm	Issue/challenge		Moderate	1 250 000	Medium	3	500 000	9	40%	17%	#NAME?	#NAME?	#NAME?	#NAME?	Equipment to recover chloride can be installed. CAPEX evaluated to Euro 650.000 in CD1.0
71	Utility	Delayed power suppy - see line 62							What are the Chances? Go to Col. 12 and	0	Level of Risk can't be calculated! - Check Col 9 and 12-	#N/A	#N/A	0,0	0,0	#NAME?	#NAME?	see line 62
72	Utility	Water supply	Kalundborg Forsyning can not supply the needed quantity of water	Risk		Major	3 500 000	Low	2	630 000	8	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	Chr. Hansen and Niras has already started the dialogue with Kalundborg Forsyning. They have already started a project of increasing supply of water to the Industries in the Kalundborg area
73	Utility	Waste water	The existing outlet pipe connecting to the public treatment plant is too small for expected amount of waste water	Issue		Minor	300 000	Low	2	54 000	4	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	Investigate the capacity of the existing pipe and start a dialogue with Kalundborg Forsyning in case the pipe is expected to be too small
74	Utility	Delivery time of equipment	Some equipment has a leadtime to long to be installed in due time. Closed: included in ID3	risk		Major	3 500 000	Medium	3	1 400 000	20	40%	17%	#NAME?	#NAME?	#NAME?	#NAME?	Contact possible suppliers to know which equipment can be a challenge to purchase, install and test before deadline. Evaluate other solutions to minimize the risk.
75	PM	Cost and time	Lack of clear definition if the project is a Food project or a Pharma project or in between and therefor what standards and procedures are required.	risk		Major	3 500 000	Medium	3	1 400 000	12	40%	17%	#NAME?	#NAME?	#NAME?	#NAME?	Define project type and update / tailor the SPO and Standards to reflect the agreed type.
76	Civils	Cost and time	If site needs to be expanded 10.000 m2 (e.g. by adding spray towers). It is necessary to buy the adjacent site/lot of land. If expansion is relevant there is a risk that the soil is of poor quality. It will be expensive to mature the site "byggemodne" and will require additional time.	Risk		Moderate	1 250 000	Low	2	225 000	6	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	Mitigating actions will depend wether or not the adjacent lot of land is to be acquired.
77	Civils	Land, cost, and time.	Layout is under pressure by the size of current site. A lack of space will affect construction, flow, and logistics. Additionally there will not be room for transformer station, solid waste handling and all additional expansions in phase 2.	Risk		Major	3 500 000	Very Low	1	175 000	4	5%	1%	#NAME?	#NAME?	#NAME?	#NAME?	2022-10-01: It has been suggested to the steering committee on the 22nd of September 2021 to purchase additional land. 2022-02-28: Scope has been reduced why the likelihood has been downgraded.
78	Civils	Geotechnics, cost, and time	Groundwater and soil conditions regarding pilotage and soil pollution are worse than expected. If the conditions are worse than expected then this will add time to the time schedule and add additional cost.	Risk		Moderate	1 250 000	Low	2	225 000	Level of Risk can't be calculated! - Check Col 9 and 12-	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	Groundwater and soil conditions regarding pilotage and soil pollution are worse than expected. If the conditions are worse than expected then this will add time to the time schedule and add additional cost. Several previous analyzes have been made. When the scope of new construction works has been clarified, supplementary environmental and geotechnical analyzes will be made. Geotechnics have been through existing documentation. Proposals for new environments and geotechnical investigations have been prepared. Cost is put into capex. The execution of the supplementary investigations is scheduled in the CD - so that they are carried out at the right time according to the project stage.
79	Civils	Construction site	A lack of space on the construction site will affect soil handling, and logistics on the site. This will entail limitations to the amount of work that can be executed simultaneously.	Risk		Moderate	1 250 000	Low	2	225 000	6	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	Awaiting clarification of potential staged construction.
80	Civils	Loads	Risk that the equipment is heavier, and loads are larger than expected. This requires additional foundations.	Risk		Moderate	1 250 000	Low	2	225 000	6	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	A part of the equipment is located on the ground. A significant buffer in the loads, but final loads will be dependent by suppliers. Awaiting clarification.
81	Civils	Sewage	Risk that the bringing sewage up to standard is expensive and complicated.	Risk		Moderate	1 250 000	Low	2	225 000	6	18%	8%	#NAME?	#NAME?	#NAME?	#NAME?	Outline main principles together with utility. NIRAS and CH continues the dialogue. Meeting regarding the main principles is recommended.

82	**Civils**	Flooding	Flooding cause by climate and more rain in proximity to the harbor. Can be destructive for buildings and production.	Risk		**Major**	3 500 000	**Very Low**	**1**	175 000	**4**	**5%**	**1%**	#NAME?	#NAME?	#NAME?	#NAME?	**NIRAS will withdraw data from the "klimakort". This is done for determining the risk for "100 års hændelsen". Chr. Hansen will consider which mitigating actions they wish to initiate. Elevating the transformers and MCC could be relevant.**
83	**Civils**	Environment	Seaside environment can take its toll on steel	Issue		**Minor**	300 000	**Medium**	**3**	120 000	**6**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	**Ventilation systems, grates, etc. must be able to be changed and the right material must be selected. Requirements for surface material incorporate in later stages.**
84	**Civils**	Environment	Soil pollution can affect rooms. If pollution is transferred to the buildings through the soil.	Risk		**Moderate**	1 250 000	**Very Low**	**1**	62 500	**3**	**5%**	**1%**	#NAME?	#NAME?	#NAME?	#NAME?	**Awaiting next phase regarding mitigating actions.**
85	**Civils**	Space	Required axillary functions for Process is not determined. Can require additional space.	Risk		**Moderate**	1 250 000	**Very High**	**5**	1 125 000	**15**	**90%**	**50%**	#NAME?	#NAME?	#NAME?	#NAME?	**We will try to collect square meter demands for these areas (cleaning, charging stations, etc.). But there will always be a risk.**
86	**Civils**	Space	Sufficient space to pipe bridges in the different sections.	Risk		**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	**A meeting has been scheduled for the 7th of October 2021 where the principles will be discussed.**
87	**Civils**	Space	If the routing for pipes is too small this can result in distribution of pipes on the roof. This is not an elegant solution and will easier wear down the roof.	Risk		**Minor**	300 000	**Low**	**2**	54 000	**4**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	
88	**Civils**	Space	Placement of technique (Vent/El) is not fully clarified. There is a risk that there will be a need for more space	Risk		**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	Ongoing. Placeholder for main installation / systems is incoporated according to the room analyzes that are being worked on. Extent of extra m2 is in progress.
89	**Civils**	Space	Is the design closed?	Risk		**Moderate**	1 250 000	**Very High**	**5**	1 125 000	**15**	**90%**	**50%**	#NAME?	#NAME?	#NAME?	#NAME?	As the main layout is not yet completely locked, it leads to greater uncertainty about capex, time, etc. Revision of the layout is expected - more land or revision of layout due to the desire to build in stages.
90	**Civils**	CAPEX	Price increases in the market. Due to COVID 19 and Ukraine crisis etc.	Risk		**Major**	3 500 000	**Very High**	**5**	3 150 000	**20**	**90%**	**50%**	#NAME?	#NAME?	#NAME?	#NAME?	A separate item/coloumn is entered in CAPEX which shows a set-aside amount for price increases
91	**Civils**	CAPEX	Current state building are planned to be located close to existing buildings. This can lead to increased unforeseen cost	Risk		**Moderate**	1 250 000	**Very High**	**5**	1 125 000	**15**	**90%**	**50%**	#NAME?	#NAME?	#NAME?	#NAME?	N/A
92	**Civils**	CAPEX	Risk that cost is uncertain due to the fact that the condition of exsisting buildings, wires etc. is not fully known	Risk		**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	Due diligense could be executed in next phase - When the dismantling of existing equipment is done in December.
93	**Civils**	3D	Layout has primarily been discussed and solved on 2D level. The entire layout should be modeled in 3D. This could result in subjects that has not been accounted for previously	Risk		**Moderate**	1 250 000	**Low**	**2**	225 000	**6**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	NIRAS will atempt to incoperate personnel flow etc. in 3D, however it will not be presentet nor discussed in this phase. Simulation in FlexSim? LMKE
94	**Civils**	Time Schedule	Stage building ("Byggeri i etaper")? This has not been discussed however it has influence / consequence on time and economy. As well as topics as - Finding the right time to apply for a new local plan, construction site layout "byggepladsindretning"	Risk		**Major**	3 500 000	**Very High**	**5**	3 150 000	**20**	**90%**	**50%**	#NAME?	#NAME?	#NAME?	#NAME?	Awaiting presentation of time schedule before any actions
95	**Civils**	Time Schedule	Late delivery time on critical building components	Risk		**Moderate**	1 250 000	**Medium**	**3**	500 000	**9**	**40%**	**17%**	#NAME?	#NAME?	#NAME?	#NAME?	Time Schedule should focus/include long lead items so that these components are visible
96	**Civils**	Time Schedule	Phase 2 - Construction on building simultaneously with ongoing operations.	Risk		**Moderate**	1 250 000	**Very High**	**5**	1 125 000	**15**	**90%**	**50%**	#NAME?	#NAME?	#NAME?	#NAME?	Depends on time schedule and further discussion in next phase. (Is vibrations etc. critical for any areas?)
97	**Civils**	Time Schedule	Risk that the timeschedule drags out resulting in the building to be forced	Risk		**Major**	3 500 000	**Low**	**2**	630 000	**8**	**18%**	**8%**	#NAME?	#NAME?	#NAME?	#NAME?	How can we force? Modular buildings? Pre construction? Awaiting for the time schedule to be presented before any actions
98	**Civils**	Tendering Strategy	Tender Strategy- Copy of NFDP?	Risk		**Moderate**	1 250 000	**Very Low**	**1**	62 500	**3**	**5%**	**1%**	#NAME?	#NAME?	#NAME?	#NAME?	Lesson learned from NFDP. The tendering strategy is being discussed by Chr. Hansen and NIRAS project management. CIVIL do not know the details of this discussion current state.
99	**Civils**	Time Schedule	New "Lokal Plan" plan is recommended, since the existing "lokal plan" is from 1982. This can have serius effect on the time schedule since this process can be very time consuming due to political approval.	RIsk on delayed start, We need to act on it.		**Major**	3 500 000	**Very Low**	**1**	175 000	**4**	**5%**	**1%**	#NAME?	#NAME?	#NAME?	#NAME?	It is of significant importance that the insertion of the application is timed properbly in the time schedule, in order to minimize risk. Chr, H/ NIRAS and Kalundborg commune had a meeting end August 2021 and 4 November 2021.
100									**What are the Chances? Go to Col. 12 and**	0	**Level of Risk can't be calculated! - Check Col 9 and 12-**	**#N/A**	**#N/A**	0,0	0,0	#NAME?	#NAME?	