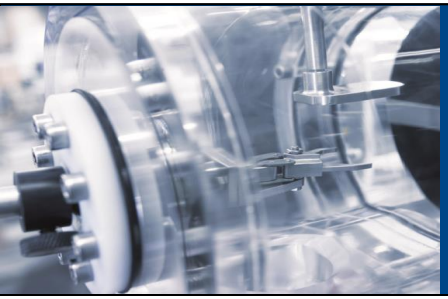
International Workshop on "Vaccine Quality Management Systems"

July 10 - 11th 2013 – Hosted by Birmex, Mexico D.F.

Plant Design and Engineering

Misha Muzikant
Operations Director South America
Telstar

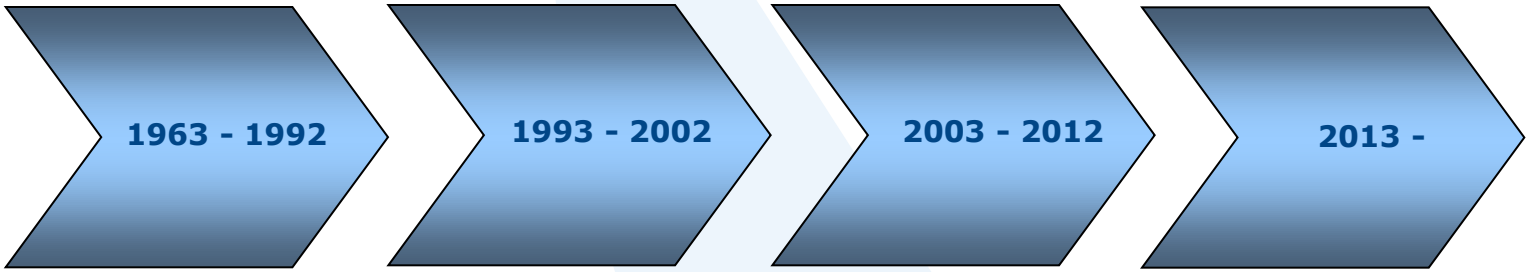


1. Who We Are

Vision

Be a global supplier for
fast track, high quality life science and
process facilities

Telstar Group Highlights



LOCAL COMPANY

EXPORT COMPANY

GLOBAL COMPANY

Life Science Division of Azbil Group

Telstar originated as a family owned company with its own brand and technology.

Telstar has a workforce of > 1000 people.

Telstar has a global scope and is established in 16 countries.

Telstar distributes its own products and services to more than 100 countries.

Total Turnover 130 M€; > 90 % generated outside Spain

Japanese Automation Firm Azbil acquires 80% Stake, Group turnover >€2 B

Telstar Group. Modular history.

Emtunga AB Modular Construction 1946

Pharmadule AB founded 1986

Pharmadule move production to Estonia, and Pharmadule OÜ founded 2005

KeyPlants AB founded 2010

Pharmadule AB liquidated 2011

KeyPlants AB and Telstar SA partners Q1 2011

Pharmadule OÜ management buy out and Telstar acquires substantial stake in 2011

The Group in the World
Telstar Group

USA

Spain

Portugal

Mexico

France

Brazil

Belgium

Argentina

UK

India

Holland

China

Ireland

Italy

Estonia

Sweden

Locations around the Globe
Telstar Group

Manufacturing Centers

Engineering, Services & Sales Offices

Telstar Worldwide facilities 25,000 m² (270,000 ft²)

Facilities
Telstar Group

Telstar Group HQ (Spain)

Life Sciences Solutions (Spain)

Telstar Technologies (Spain)

Telstar Life Sciences (UK)

Facilities
Telstar Group

Telstar Far East (China)

Telstar North America (USA)

Telstar Medical Components (Holland)

Telstar Clean Air (Holland)

Telstar (Estonia)

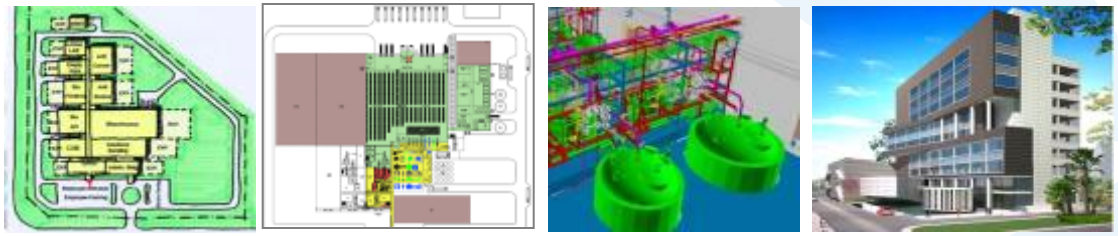
EPC/MV
Capabilities

LIFE SCIENCE CAPABILITIES:

We deliver one stop shop solutions for the Life Sciences Industry - from initial Site selections and Feasibility studies, to Concept/ Basic/ Detail Design moving into Construction and Commissioning/ IQ/ OQ as well as Validation - in short the whole project Life cycle.

Qualification / Validation

Project Management & Construction



Consultation / Engineering

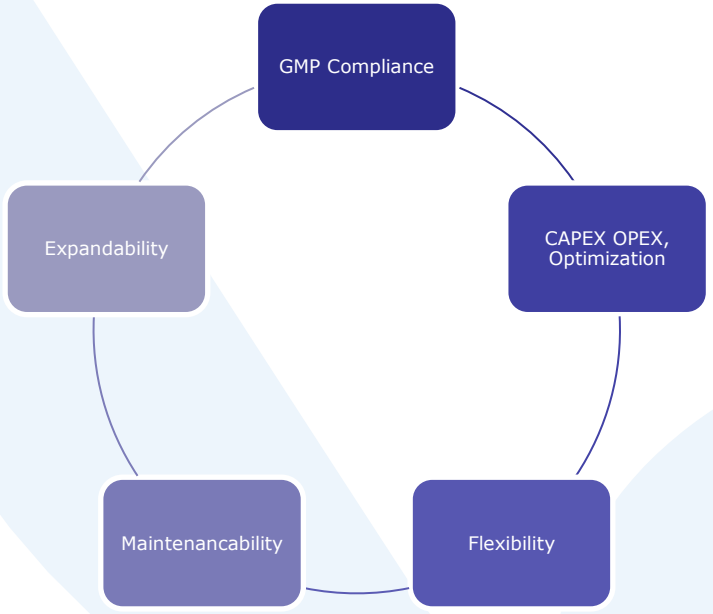
Modular Offerings

- Project Types
  - Green field/Brown field
  - Upgrades, expansions and renovations
- Complete Range of Modular Solutions
  - Building Modules (Out-door/In-door)
  - Box in box solutions
  - Process Modules/Skids
  - Complete Standardized Facilities
- Project Delivery Options
  - From feasibility study to Turn-Key delivery
  - (Out-door/In-door/Hybrid)
  - Off-site construction for any Project

Engineering

Design Philosophy

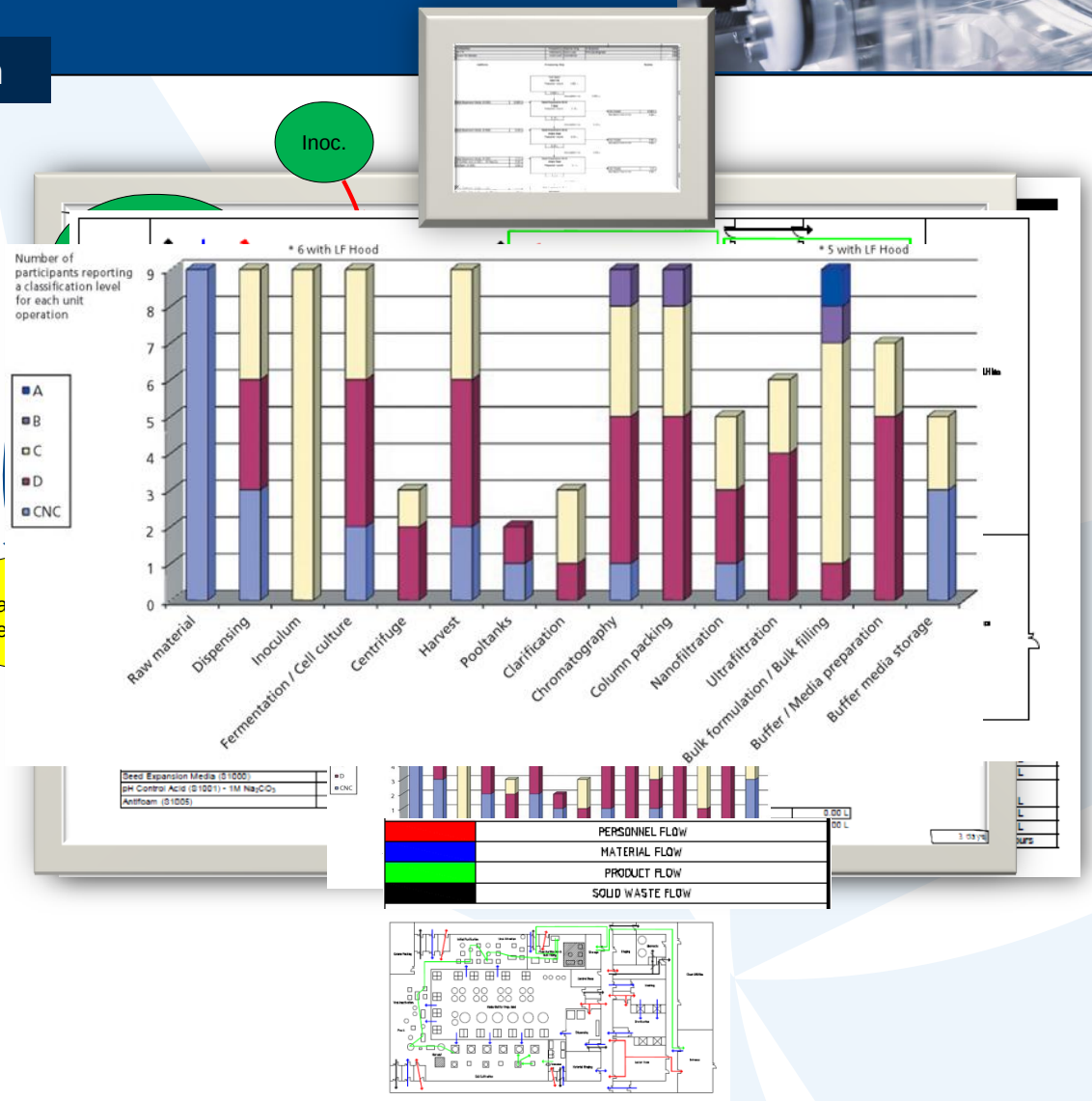
- Design simplicity and efficiency will be a prime consideration.
- Design for constructability
- Design to budget & optimise cost
- Design for local conditions
- Design for available materials and suppliers
- Design with known quality products
- Design to avoid risk
- Design for maintenance efficiency



Process Layout Development

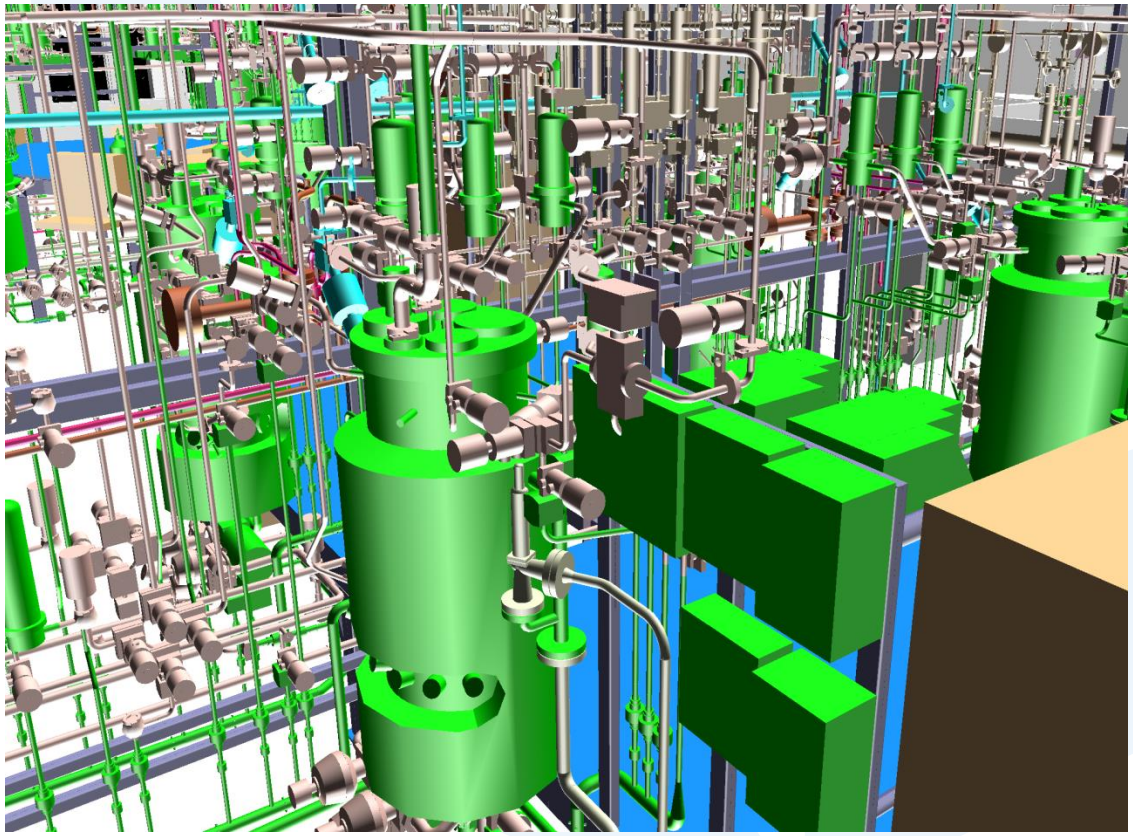
Basic Principle: Form follows function

1. Visualisation of process flows by block-flow-diagrams
2. Process model
3. Adjacency / bubble diagrams (functional relations of separate neighbourhood units)
4. Areas and surfaces
5. Functional layout with zoning, material and personal flows



Engineering
Tools

Design Option "3D Plant Engineering for Complex Plants and Areas"



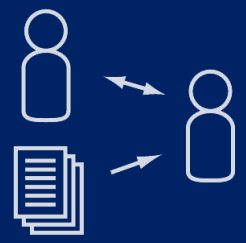
Advantages:

- Space Management and inter-discipline design coordination
- Generation of isometric drawings
- automatic material take-off for purchase orders
- Customer-specific piping classes

Front End Design and Delivery in 5 Steps

A Proven Approach

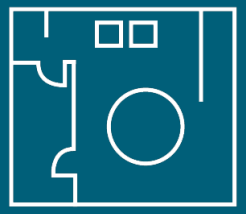
Technology Transfer



1 Week 1

- Existing Data Transfer from Client

Concept Design



3 Weeks 2

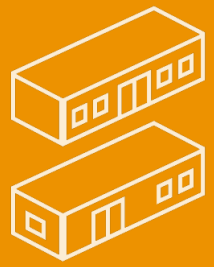
- Architectural BOD:
  - Adjacency diagrams
  - Layout sketches
- Mechanical BOD:
  - Classification drawings
  - Zoning drawings
- Electrical BOD:
  - Single line diagram
- Site and Structural BOD:
  - Initial layouts
  - Structural grid plan
- Conceptual Cost & Schedule

Design Alt. Team Meeting

1 Week 3

- OOM Estimate
- Level 1 Schedule
- Design Review

Concept Optimization



2 Weeks 4

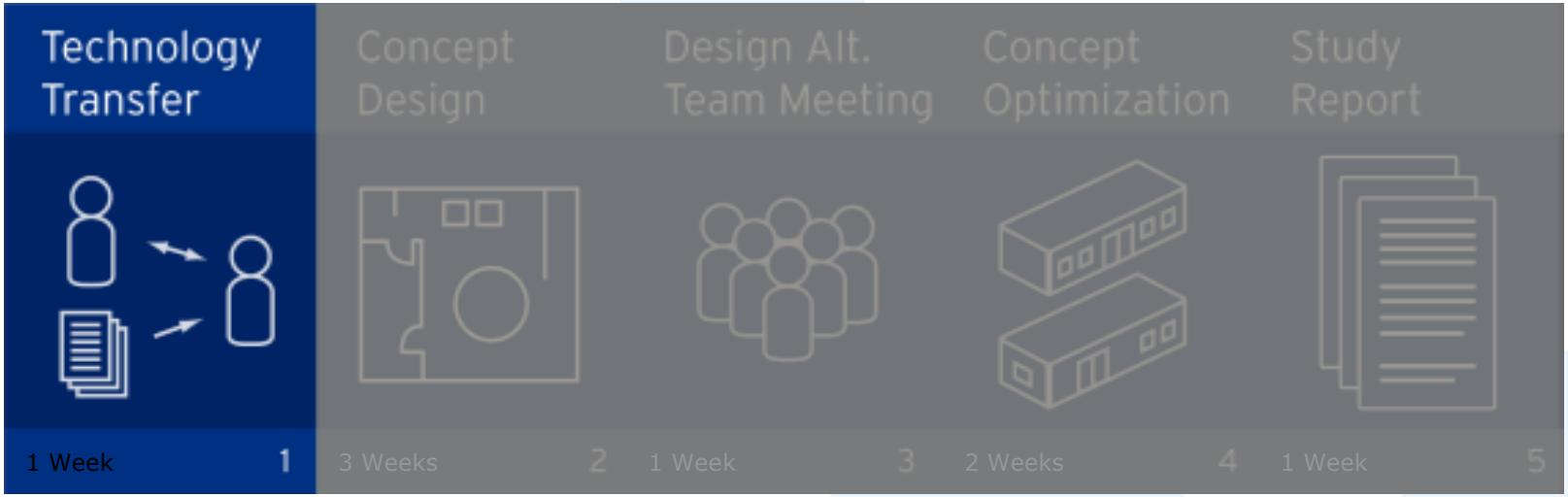
- Concept Design Data Finalized
- "What if's" Completed
- OOM Estimate
- Schedule
- Comments on Draft Design Report

Study Report

1 Week 5

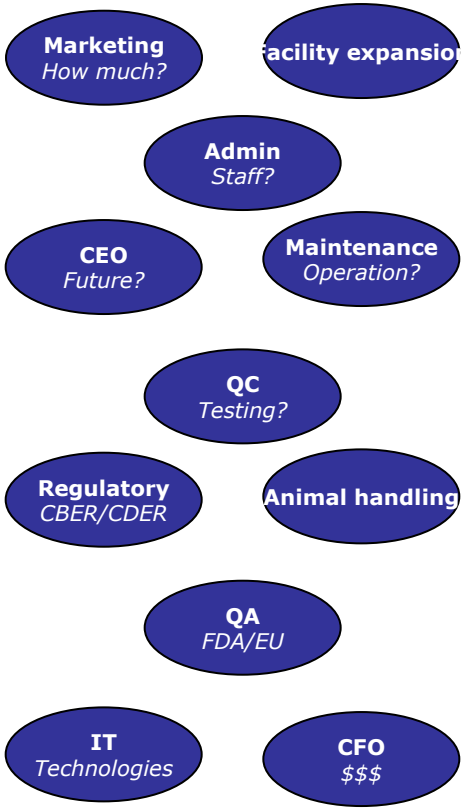
- Issue Concept Design Report

Step 1 – Technology Transfer



Step 1 – Alignment

- Step 1 is to achieve alignment with the goals and expectations of the customer's stakeholders. Key project goal-setting criteria involve the following.



Challenges

- Scope definition
- Site limitations, multiple sites,
- Define existing systems
- Clear vision
- Interface with client
- Integration of lab/vivarium operations
- Implementation of corporate standards
- Budget
- Time frame
- Understanding animals/personnel segregation
- Expansion capabilities

Goal: Define present and future challenges, set objectives and project goals

Process and Operational Requirements & Facility Optimization

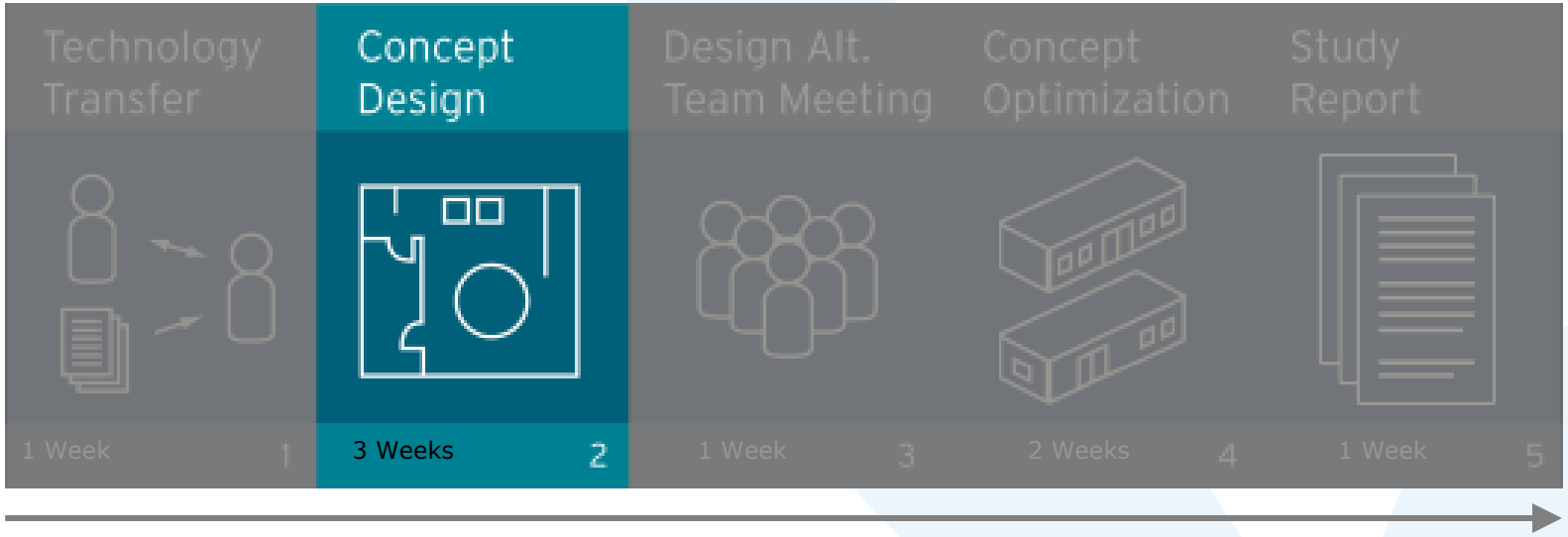
Process Requirements :

- Nature of research being conducted
- Strict control of physical environment
- Introduction Quarantine/ disease prevention
- Type and size of animals
- Number of different species
- Isolation of species and control groups
- Proper disposal of waste/ Incineration
- Barriers to prevent cross contamination

Facility Design:

- Circulation/flows
- Animal Quarantine
- Animals and Equipment access
- Expansion requirements
- Finishes/materials of construction
- Animal Wash Down system
- NIH Compliance
- Animal Watering System
- Redundant 100% outside air systems

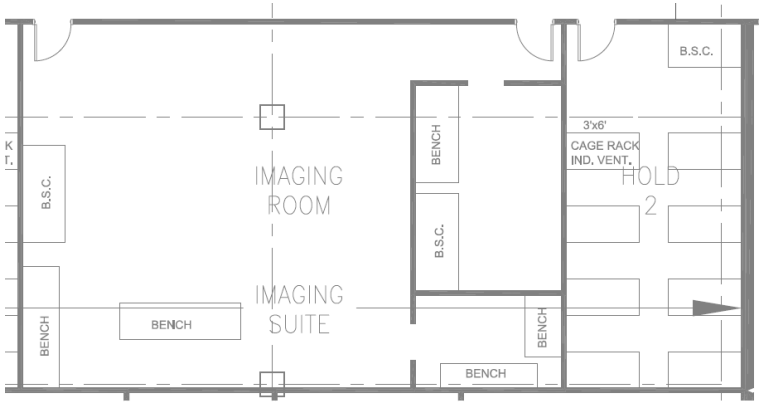
Master Planning Approach – Program Definition



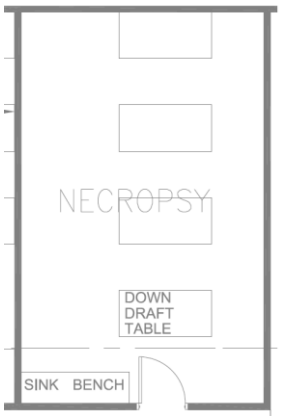
Step 2 – General Process Room Criteria

- **Telstar integrated team approach**
  - Architecture – seamless floor, sizing, critical adjacencies
  - HVAC – Air supply and exhaust filtered to remove dust and hair, room at negative pressure related to corridor, sensors to monitor temperature and humidity
  - Structural – floor loading at 125 to 150 psf minimum
  - Electrical – equipment and systems requirements, distribution
  - Plumbing – 15 sm – diameter minimum floor drain with strainer, solids trap, disposal unit, and threaded cover, not required for rodent rooms

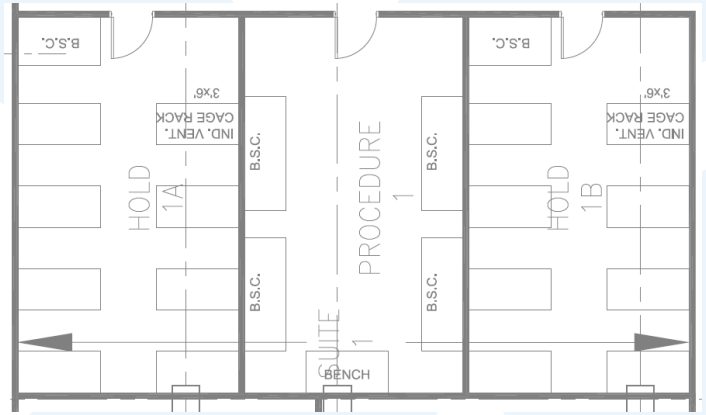
Imaging Suite



Necropsy

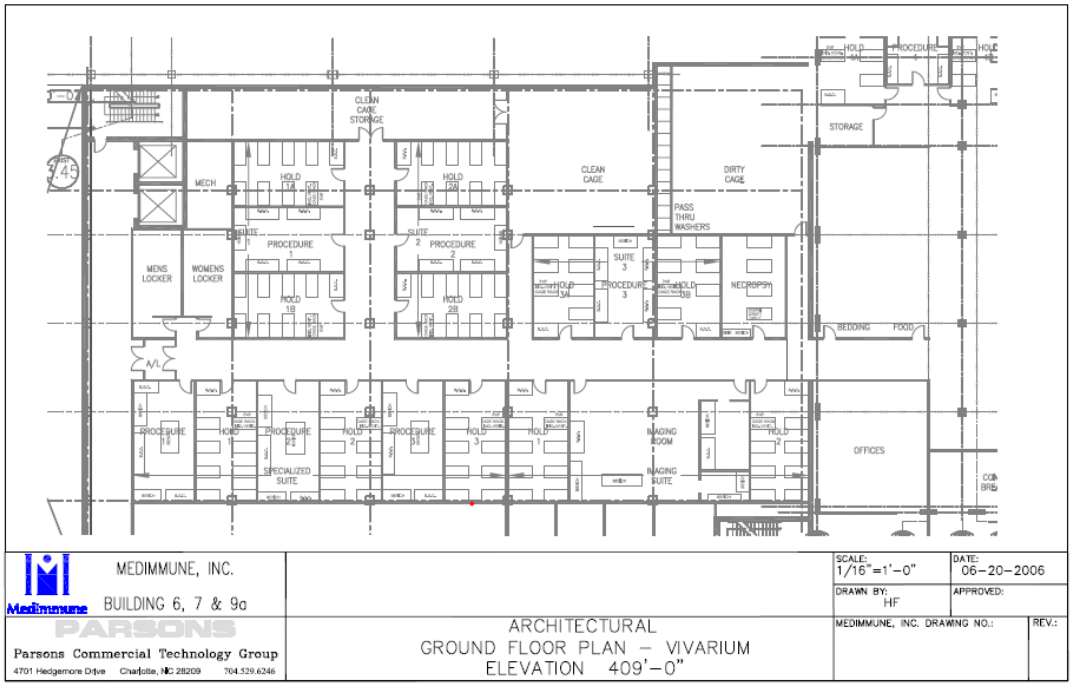


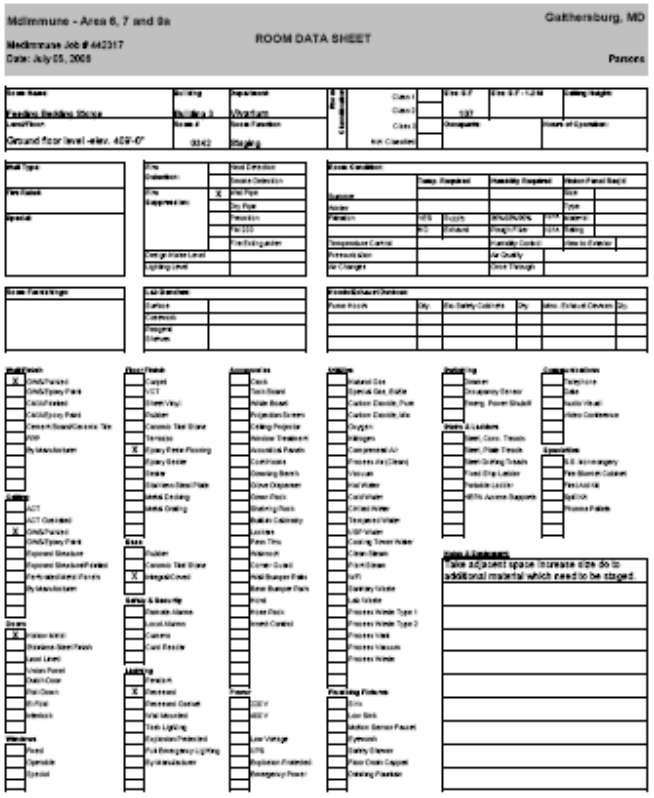
Procedure Suite 1



Master Planning Approach – Design Basis and Program Definition

Room Data Sheet





Programming

Architectural Program

MedImmune

Parsons Life Sciences Group

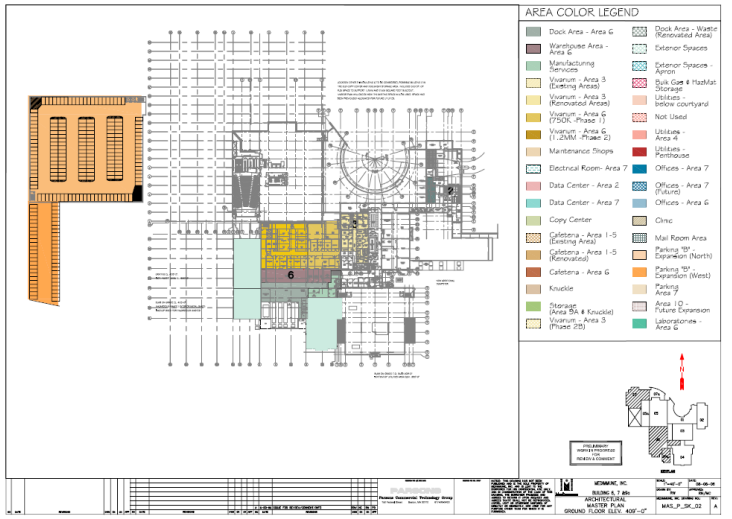
MEDIMMUNE
Gaithersburg, MD
ARCHITECTURAL SPACE PROGRAM - Vivarium

Rev. - C
Oct. 10, 2006

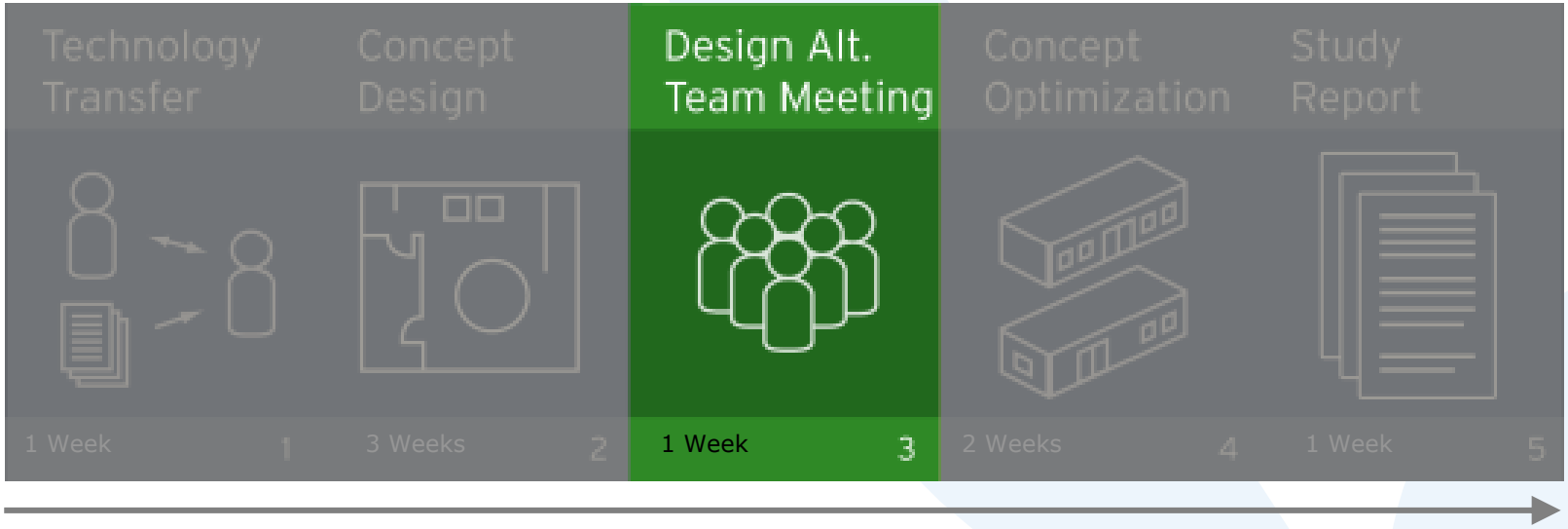
Rm No	Room Name	Existing Space	Potential Space Modifications to Existing Area	Phase 1 Expansion - Program Ft²	Phase 2 Expansion - Program Ft²	Length	Width	Comments	Equipment
	Level 1: Ground Floor 489'-0"								
	New Vivarium Space - Area 6								
	Existing Spaces in Area 3								
	Cage Wash and Bedding Area								
	Clean Cage Staging/Storage	237						Space is throughput dependent. May not need to add space for washing more cages	
	Clean Cage Wash	515						Space is throughput dependent. May not need to add space for washing more cages	
	Dirty Cage Wash	704						Addition space will come from modifications to existing space. Adjacent Maintenance areas could be relocated	
	Feeding Bedding Storge	107						Take adjacent space. Increase size due to additional material which needs to be staged	
	Quarantine	88						Quilty Controlled now, Adjacent to but not in Vivarium	
	Rodent Rooms								
	Rodent Rooms 1	335							
	Rodent Rooms 2	335							
	Rodent Rooms 3	204							
	Rodent Rooms 4	204							
	Rabbit Housing Suite								
	Rabbit housing room 1	187							
	Rabbit housing room 2	176							
	Rabbit housing room 3	310							
	Procedure Suite								
	Procedure Room 1	205							
	Procedure Room 2	211							
	Scrub Room	130							
	Prep Room 1	141							
	Prep Room 2	141							
	Air Handler Room	800							
	Possible adds to Existing Space								
	Radiation Room	100							
	Necropsy Room		367					Surgical Autopsy	4 Downdraft tables Scrub sink
	Secondary Storage Room		100						
	Sub-Totals	4230	467	0	0				

Rooms Kit, Adjacencies

Color Block Diagram



Master Planning Approach – Team Workshop



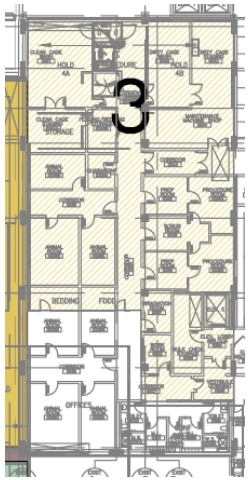
Step 3 – Team Workshop

- Facility block diagrams
- Animal, personnel, equipment and waste flow
- Code research results
- Order of magnitude cost estimates
- Adjacency diagrams
- Initial programming of spaces
- Confirmation of design with Animal Care and Use Committee

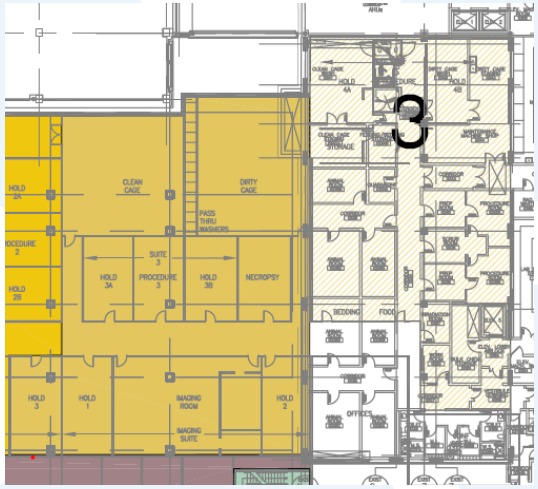
Master Planning Approach - Stage 1 and 2

Legend

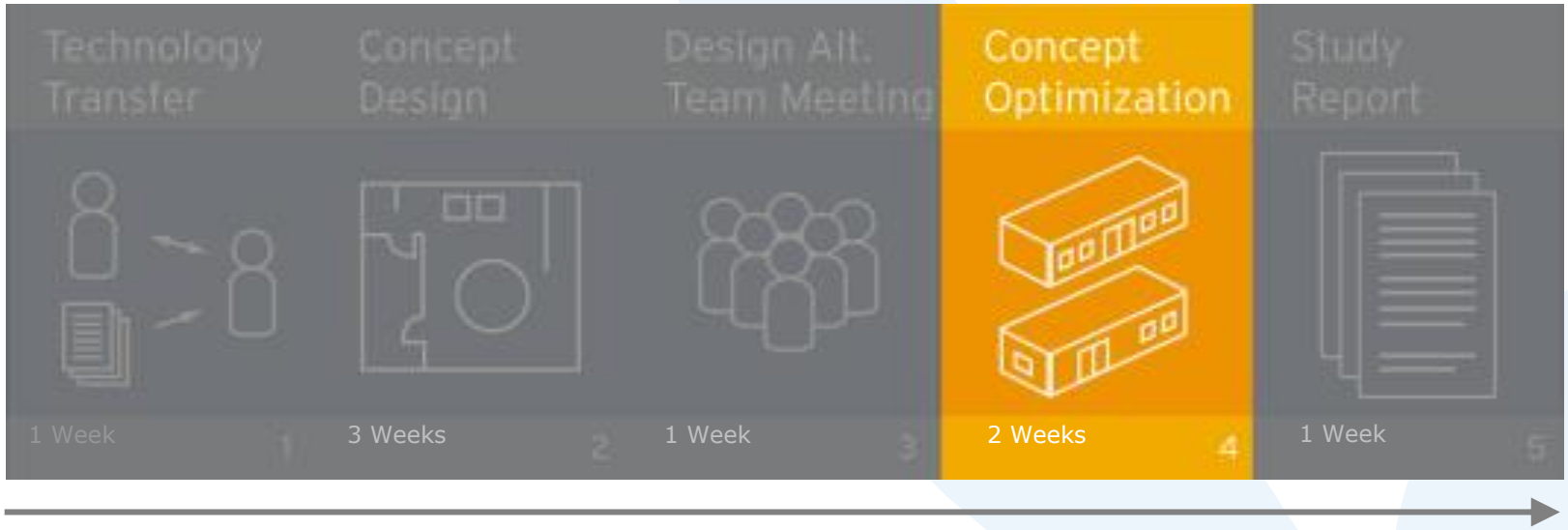
- Vivarium - Area 3 (Existing Areas)
- Vivarium - Area 3 (Renovated Areas)
- Vivarium - Area 6 (750K -Phase 1)
- Vivarium - Area 6 (1.2MM -Phase 2)



Stage 1 Construction



Master Planning Approach – Concept Development



Comments on Draft Design Report

- Feedback comments from the client to be integrated into final concept realization model

10 Aug. 2006 Decision Made:

- Vivarium users are generally satisfied with size of Phase One Expansion location and adjacencies.
- Isolated slab and sound insulation of the Vivarium area.
- Vivarium users are open to the issue of Wash Area in Expansion Phase 2 as a leading element.
- ROD should be provided by the water supply system.
- Keep BL2 connection for transfer of materials to the Labs.
- Machine Room space is going is going to be available to potential use for Necropsy. (2009)
- The Entry into Vivarium would be through the Locker Rooms Gowning Room.

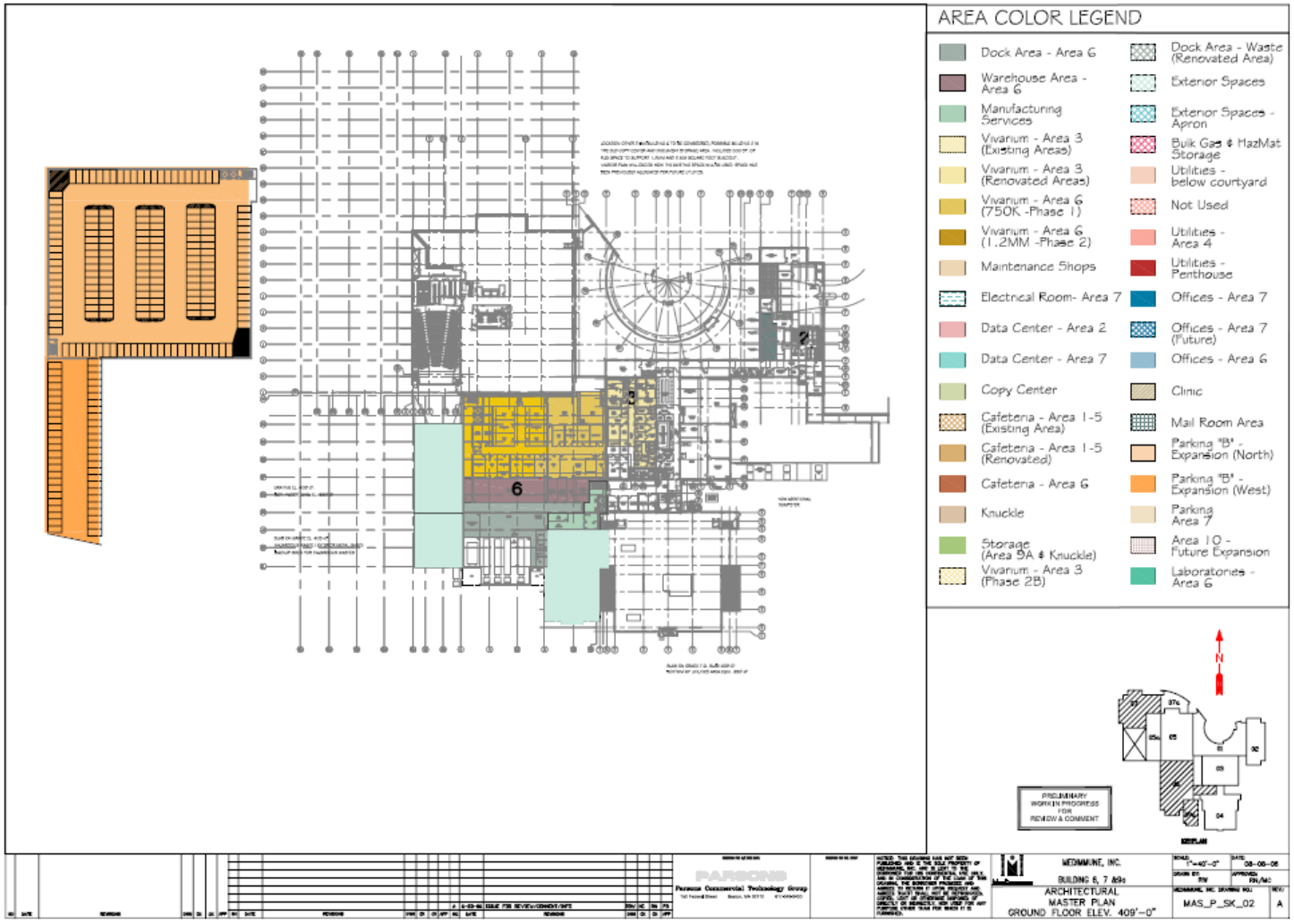
Imaging Suite:

- 36" aisle size in the existing Housing Room is the guideline for the Housing Room Layout.
- Adjoining door requirement is for frequency of use, also the Housing Rooms are dedicated to Imaging Procedure Room.
- Intraviral Microscopy System - requires a separate room. Prep., surgery, anesthesia and microscope work. (Bench - 3'-0" x 3'-0", 3'-0" x 4'-0", computer)
- Plethsmography Chambers - open space requirement, (2) 6'-0" tables and computer

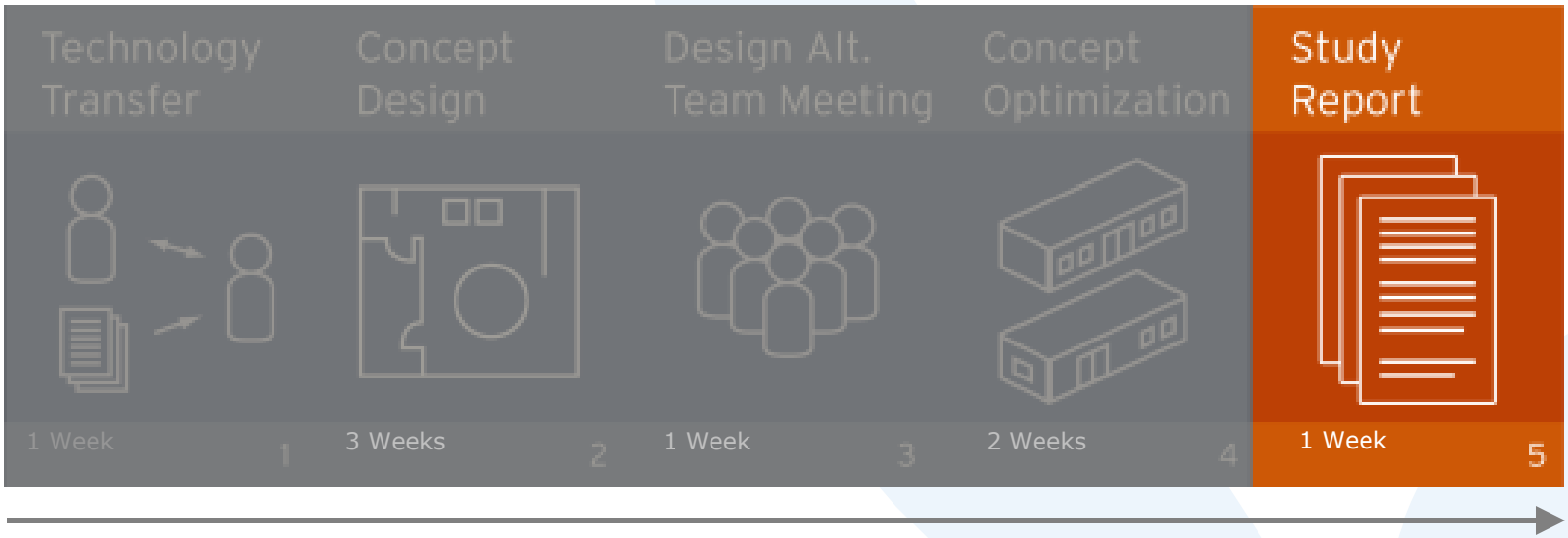
10 Aug, 2006 Decision Made: Notes by Dan Walsh - 14 Aug. 2006

1. The comment on RODI was made to be sure that the system is sized for the needs of the animal watering system.
2. The transfer of the machine shop space for use by the Vivarium will be made when the machine shop moves to Area 4 in the 1st Qtr of 2007. Thus the design for same needs to preceded that by being done in 2006.
3. The microscope room may also have a requirement for darkening and so needs to be so constructed.

Step 4: Concept Optimization, Integration – Overall Master Plan



Master Planning Approach – Concept Realization

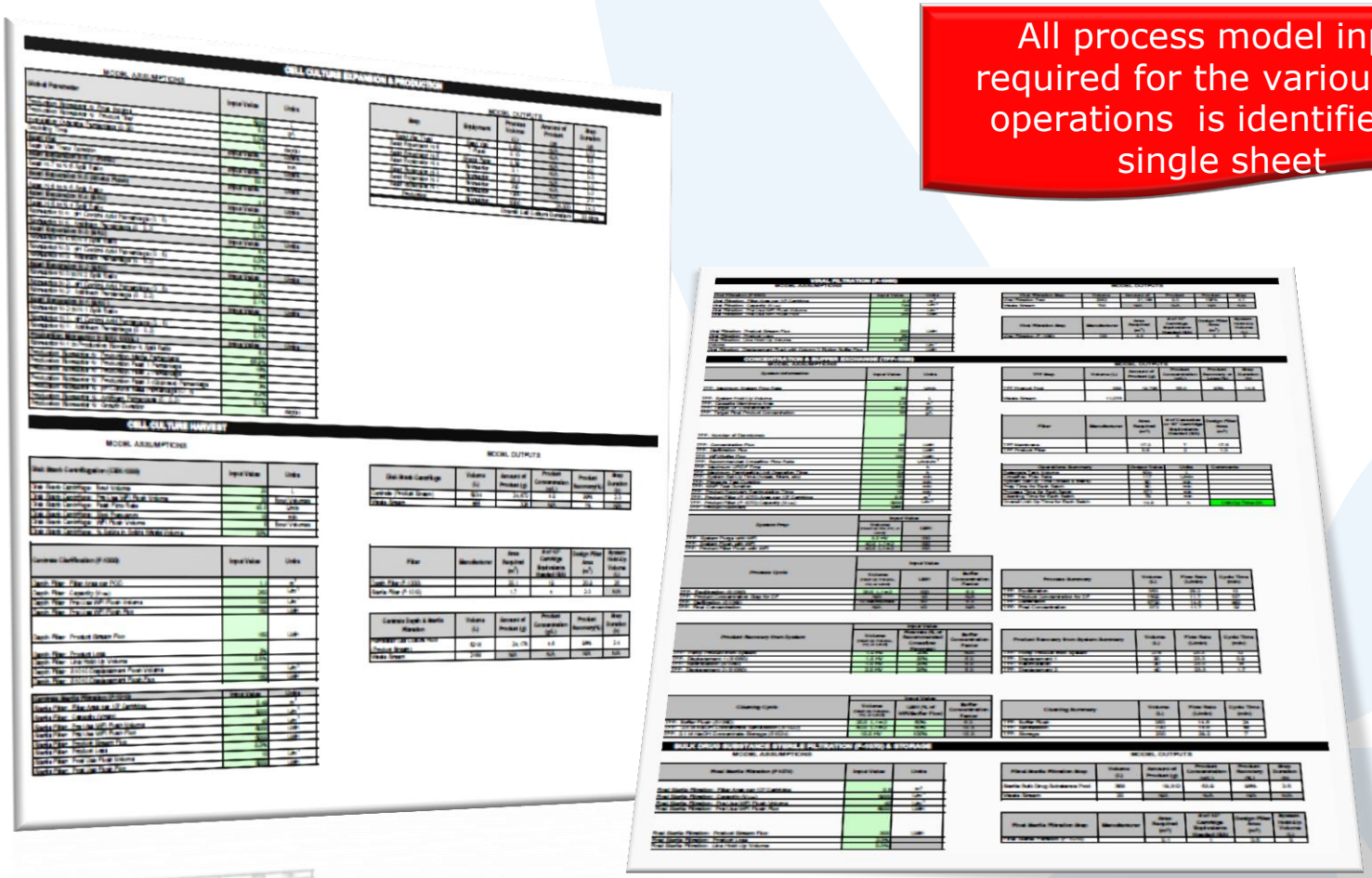


Step 5 – Final Report and 3-D Model

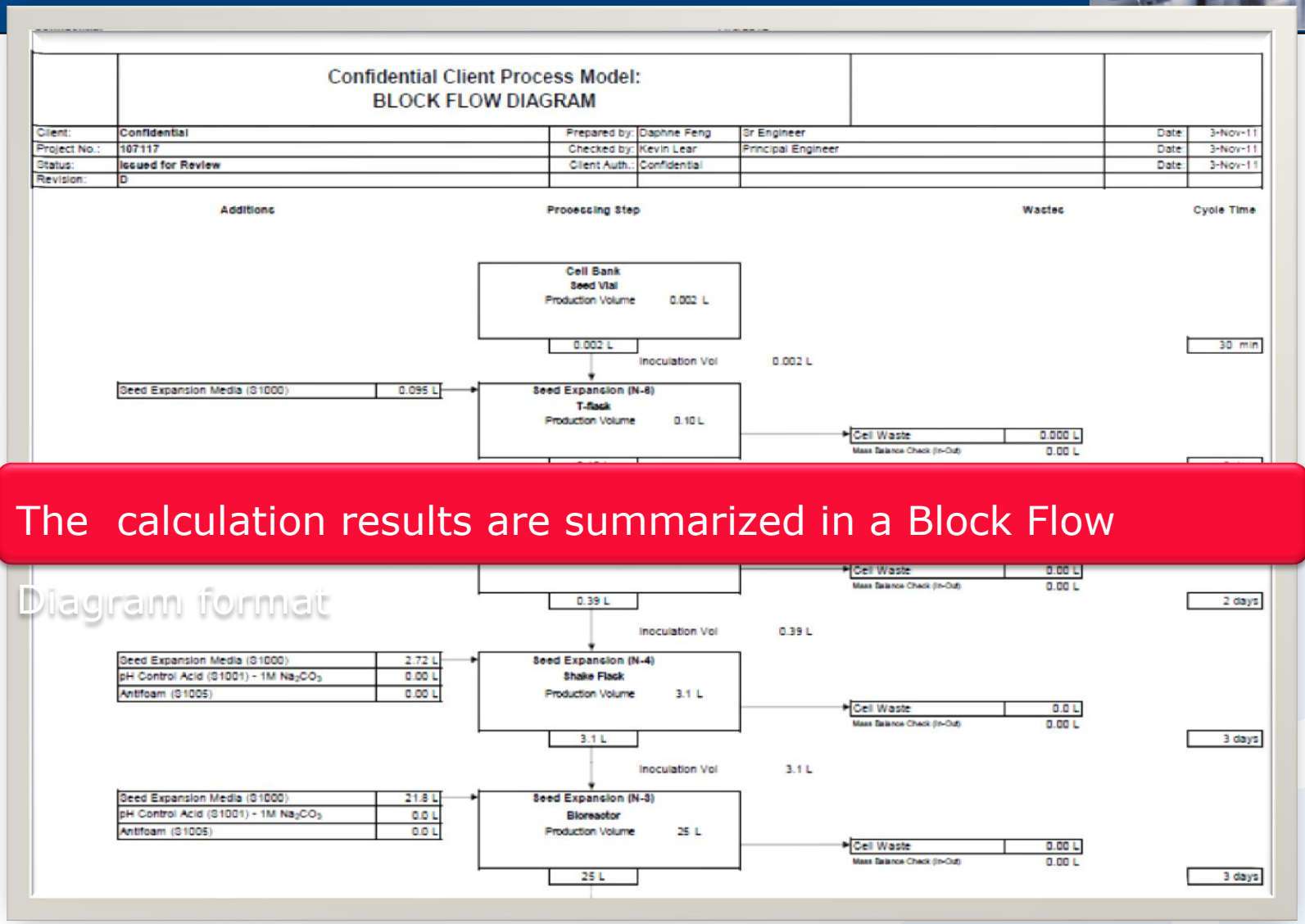
- Review/Example of Facility Concept Modeling

Process Model – Input

All process model input required for the various unit operations is identified on single sheet



Process Model – Output in Block Flow Diagram



The calculation results are summarized in a Block Flow Diagram format

Media and Buffer Equipment

A-MAB BUFFER SUMMARY

	Description	Concentration Factor	Area	Volume Req'd	Prep Overage	Prep Volume (+20%)	Prep Tank WV (L)	Prep Tank Number	
	Seed Expansion Media	1 X	Media Prep	200 L	10%	220 L	1000 L	T-1102	N/A tranfer
1000	Seed Expansion Media	1 X	Media Prep	799 L	10%	879 L	1000 L	T-1102	None, Direct tranfer to BR
S1001	Cell Culture pH Control Acid - ~1M Na_2CO_3	1 X	Buffer Prep	150 L	20%	180 L	500 L	T-1203	250 L
S1002	Production Media	1 X	Media Prep	2795 L	5%	2935 L	4500 L	T-1101	None, Direct tranfer to BRX
S1003	Production Feed 1	1 X	Media Prep	750 L	5%	788 L	1000 L	T-1102	500 L
S1004	Production Feed 2	1 X	Media Prep	150 L	20%	180 L	1000 L	T-1102	200 L
S1005	Production Feed 3 (Glucose)	1 X	Buffer Prep	150 L	20%	180 L	500 L	T-1203	200 L
S1006	Antifoam	1 X	Media Prep	6 L	20%	7 L	None	NA	10 L
S1010	Harvest Filtration Flush Buffer	1 X	Buffer Prep	209 L	20%	251 L	500 L	T-1203	500 L
S1020	Acid for Viral Inactivation	1 X	Buffer Prep	121 L	220%	387 L	500 L	T-1203	500 L
S1021	Base for Viral Inactivation	1 X	Buffer Prep	127 L	220%	406 L	500 L	T-1203	500 L
S1022	0.5M NaOH (Concentrate)	10 X	Buffer Prep	1632 L	130%	3754 L	2000 L	T-1201	3785 L
S1024	0.1M NaOH (Concentrate)	10 X	Buffer Prep	129 L	0%	129 L	0 L	NA	Use S1022
S1030	ProA Equilibration/Wash 1/Wash 3 Buffer (Concentrat	5 X	Buffer Prep	1088 L	20%	1306 L	2000 L	T-1201	1500 L
S1032	ProA Wash 2 Buffer (Concentrate)	5 X	Buffer Prep	363 L	20%	435 L	500 L	T-1203	500 L
S1034	ProA Elution Buffer (Concentrate)	5 X	Buffer Prep	566 L	20%	679 L	1000 L	T-1202	1000 L
S1035	ProA Regeneration Buffer (Concentrate)	5 X	Buffer Prep	242 L	20%	290 L	500 L	T-1203	500 L
S1036	Chromatography Integrity Test Injection Solution	1 X	Buffer Prep	0.4 L	20%	0 L	Bench	NA	1 L
S1037	ProA Load Conditioning Buffer (Concentrate)	5 X	Buffer Prep	0 L	20%	0 L			
S1040	Column 2 Equilibration Buffer (Concentrate)	5 X	Buffer Prep	1166 L	20%	1399 L	2000 L	T-1201	1500 L
S1042	Column 2 Wash 2 Buffer (Concentrate)	5 X	Buffer Prep	583 L	20%	700 L	1000 L	T-1202	1000 L
S1044	Column 2 Elution Buffer (Concentrate)	5 X	Buffer Prep	1050 L	20%	1259 L	2000 L	T-1201	1500 L
S1047	Column 2 Load Conditioning Buffer (Concentrate)	5 X	Buffer Prep	0 L	20%	0 L			
S1050	Column 3 Equilibration Buffer (Concentrate)	5 X	Buffer Prep	1126 L	20%	1351 L	2000 L		
S1052	Column 3 Wash 2 Buffer (Concentrate)	5 X	Buffer Prep	302 L	20%	363 L	500 L		
S1054	Column 3 Elution Buffer (Concentrate)	5 X	Buffer Prep	1019 L	20%	1223 L	2000 L		
S1057	Column 3 Load Conditioning Buffer (Concentrate)	5 X	Buffer Prep	0 L	20%	0 L			
S1060	TFF Buffer (Concentrate)	5 X	Buffer Prep	1497 L	20%	1796 L	2000 L		

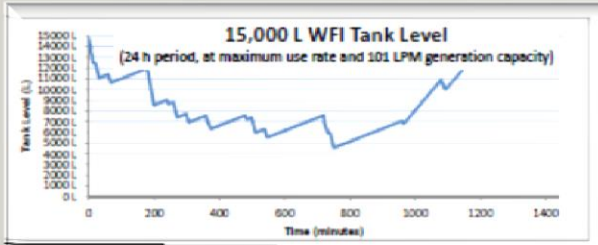
TOTAL UPSTREAM 4740 L
TOTAL DOWNSTREAM 16358 L
TOTAL 21098 L

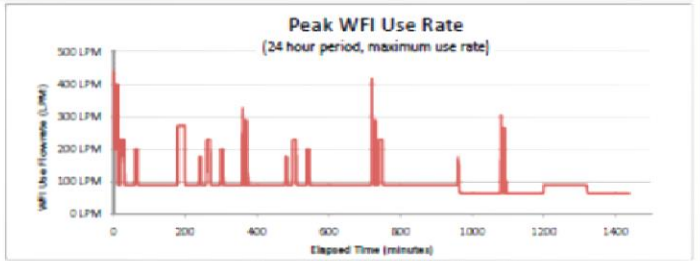
Page 1 of 1

Media P

Output from the process model is used to size media and buffer prep and hold equipment

Process Model – Clean Utility

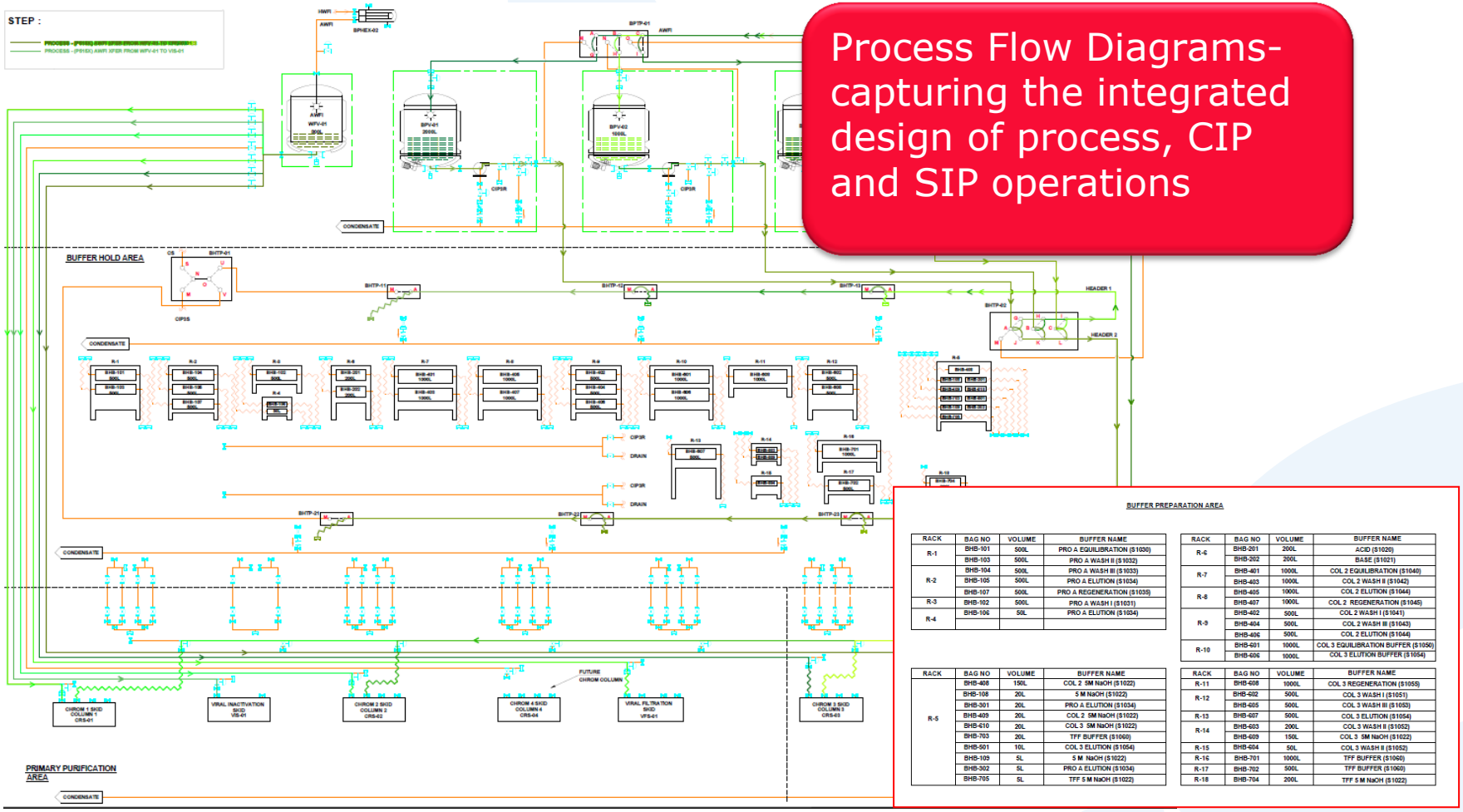




Tank Volume		15000 L																		
Minimum Tank Level		4651 L					AMBIENT WFI USE						HOT WFI USE (CLEANING)							
Design WFI Generation		101 LPM	Media Prep Mix Tank		Buffer Prep Mix Tank			Protein A Chromatography	Column 2 Chromatography	Column 3 Chromatography	TFF Skid-1	Misc Use	HCCF Tank	Production BRX	Equipment washer		CS Supply	Peak HWFI	Peak AWFI
Minimum WFI Generation		97	4500 L	1300 L	2000 L	1000 L	500 L						6,000	5,000					
Peak WFI Use		437 LPM	184 LPM	110 LPM	140 LPM	111 LPM	88 LPM	24 LPM	24 LPM	24 LPM	12 LPM	40 LPM	100 LPM	100 LPM	38 LPM	38 LPM	25 LPM	Max	Max
		Use Duration	20 min	12 min	11 min	9 min	5 min	16 h	2 h	0 h	0 h	24 h	3 min	3 min	3 min	3 min	24 h	238 LPM	248 LPM
		Number of Users	1	1	4	3	4						8	8	4	4			
Time (min)	Tank Level	Peak WFI USE																	
1	14664 L	437 LPM		110 LPM				24 LPM				40 LPM	100 LPM	100 LPM	38 LPM		25 LPM	238 LPM	174 LPM
2	14328 L	437 LPM		110 LPM				24 LPM				40 LPM	100 LPM	100 LPM	38 LPM		25 LPM	238 LPM	174 LPM
3	14191 L	237 LPM		110 LPM				24 LPM				40 LPM			38 LPM		25 LPM	38 LPM	174 LPM
4	14093 L	100 LPM		110 LPM				24 LPM				40 LPM					25 LPM	0 LPM	174 LPM
5	13995 L	100 LPM		110 LPM				24 LPM				40 LPM					25 LPM	0 LPM	174 LPM
6	13897 L	399 LPM		110 LPM				24 LPM				40 LPM	100 LPM	100 LPM			25 LPM	200 LPM	174 LPM
7	13399 L	399 LPM		110 LPM				24 LPM				40 LPM	100 LPM	100 LPM			25 LPM	200 LPM	174 LPM
17	12454 L	89 LPM						24 LPM				40 LPM					25 LPM	0 LPM	64 LPM
		89 LPM						24 LPM				40 LPM					25 LPM	0 LPM	64 LPM
		89 LPM						24 LPM				40 LPM					25 LPM	0 LPM	64 LPM
20	12490 L	89 LPM						24 LPM				40 LPM					25 LPM	0 LPM	64 LPM
21	12361 L	229 LPM			140 LPM			24 LPM				40 LPM					25 LPM	0 LPM	204 LPM
22	12233 L	229 LPM			140 LPM			24 LPM				40 LPM					25 LPM	0 LPM	204 LPM
23	12105 L	229 LPM			140 LPM			24 LPM				40 LPM					25 LPM	0 LPM	204 LPM
24	11977 L	229 LPM			140 LPM			24 LPM				40 LPM					25 LPM	0 LPM	204 LPM
25	11848 L	229 LPM			140 LPM			24 LPM				40 LPM					25 LPM	0 LPM	204 LPM
26	11720 L	229 LPM			140 LPM			24 LPM				40 LPM					25 LPM	0 LPM	204 LPM
27	11592 L	229 LPM			140 LPM			24 LPM				40 LPM					25 LPM	0 LPM	204 LPM
28	11464 L	229 LPM			140 LPM			24 LPM				40 LPM					25 LPM	0 LPM	204 LPM
29	11335 L	229 LPM			140 LPM			24 LPM				40 LPM					25 LPM	0 LPM	204 LPM
30	11207 L	229 LPM			140 LPM			24 LPM				40 LPM					25 LPM	0 LPM	204 LPM
31	11079 L	229 LPM			140 LPM			24 LPM				40 LPM					25 LPM	0 LPM	204 LPM
32	11091 L	89 LPM						24 LPM				40 LPM					25 LPM	0 LPM	64 LPM
33	11103 L	89 LPM						24 LPM				40 LPM					25 LPM	0 LPM	64 LPM
34	11115 L	89 LPM						24 LPM				40 LPM					25 LPM	0 LPM	64 LPM
35	11127 L	89 LPM						24 LPM				40 LPM					25 LPM	0 LPM	64 LPM
36	11139 L	89 LPM						24 LPM				40 LPM					25 LPM	0 LPM	64 LPM
37	11151 L	89 LPM						24 LPM				40 LPM					25 LPM	0 LPM	64 LPM

Utility estimates are based on the process model results and production schedule

Process Diagram



Process Flow Diagrams- capturing the integrated design of process, CIP and SIP operations

BUFFER PREPARATION AREA

RACK	BAG NO	VOLUME	BUFFER NAME
R-1	BHB-101	500L	PRO A EQUILIBRATION (S1030)
	BHB-103	500L	PRO A WASH II (S1032)
R-2	BHB-104	500L	PRO A WASH III (S1033)
	BHB-105	500L	PRO A ELUTION (S1034)
	BHB-107	500L	PRO A REGENERATION (S1035)
R-3	BHB-102	500L	PRO A WASH I (S1031)
R-4	BHB-106	50L	PRO A ELUTION (S1034)

RACK	BAG NO	VOLUME	BUFFER NAME
R-5	BHB-408	150L	COL 2 5M NaOH (S1022)
	BHB-108	20L	5 M NaOH (S1022)
	BHB-301	20L	PRO A ELUTION (S1034)
	BHB-409	20L	COL 2 5M NaOH (S1022)
	BHB-610	20L	COL 3 5M NaOH (S1022)
	BHB-703	20L	TFF BUFFER (S1060)
	BHB-501	10L	COL 3 ELUTION (S1054)
	BHB-109	5L	5 M NaOH (S1022)
	BHB-302	5L	PRO A ELUTION (S1034)
	BHB-705	5L	TFF 5 M NaOH (S1022)

RACK	BAG NO	VOLUME	BUFFER NAME
R-6	BHB-201	200L	ACID (S1026)
	BHB-202	200L	BASE (S1021)
R-7	BHB-401	1000L	COL 2 EQUILIBRATION (S1040)
	BHB-403	1000L	COL 2 WASH II (S1042)
R-8	BHB-405	1000L	COL 2 ELUTION (S1044)
	BHB-407	1000L	COL 2 REGENERATION (S1045)
R-9	BHB-402	500L	COL 2 WASH I (S1041)
	BHB-404	500L	COL 2 WASH III (S1043)
	BHB-406	500L	COL 2 ELUTION (S1044)
R-10	BHB-601	1000L	COL 3 EQUILIBRATION BUFFER (S1050)
	BHB-606	1000L	COL 3 ELUTION BUFFER (S1054)

RACK	BAG NO	VOLUME	BUFFER NAME
R-11	BHB-608	1000L	COL 3 REGENERATION (S1055)
R-12	BHB-602	500L	COL 3 WASH I (S1051)
	BHB-605	500L	COL 3 WASH III (S1053)
R-13	BHB-607	500L	COL 3 ELUTION (S1054)
R-14	BHB-603	200L	COL 3 WASH II (S1052)
	BHB-609	150L	COL 3 5M NaOH (S1022)
R-15	BHB-604	50L	COL 3 WASH II (S1052)
R-16	BHB-701	1000L	TFF BUFFER (S1060)
R-17	BHB-702	500L	TFF BUFFER (S1060)
R-18	BHB-704	200L	TFF 5 M NaOH (S1022)

Dynamic Simulation Production Process
Production Optimization

Projected Equipment Utilization

Production Schedule for 2 X 5000 L Bioreactor Trains and 1 Purification/week

	Equipment in Operation								
Day	TRAIN 1	TRAIN 2	TRAIN 1	TRAIN 2	TRAIN 1	BOTH TRAINS	Equipment for CIP/SIP Operation	Media Prep Operation	Buffer Prep Operation
1	0,1					INC-01			
2	0,1					INC-01			
3	0,1					INC-01			
4	0,1					INC-01			
5	0,1					INC-01			
6	0,39					INC-01			
7	0,39	0,1				INC-01			
8	3	0,1				INC-01, INC-02			
9	3	0,1				INC-01, INC-02			
10	3	0,1				INC-01, INC-02			
11	25	0,1				INC-01, INC-02			
12	25	0,39				INC-01, INC-02		1000 L	
13	25	0,39				INC-01, BRV-01			
14	200	3				INC-02, BRV-02			
15	200	3	0,1			INC-01, INC-02, BRV-02			
16	200	3	0,1			INC-01, INC-02, BRV-02	1000L BRV1	1000 L	
17	1000	25	0,1			INC-01, BRV-01, BRV-03		1000 L, 1000 L, 1000 L	
18	1000	25	0,1			INC-01, BRV-01, BRV-03	5000 L BRV1	5000, 1000 L	
19	5000	25	0,1			INC-01, BRV-01, BRV-04			
20	5000	200	0,39			INC-01, BRV-02, BRV-04			
21	5000	200	0,39	0,1		INC-01, BRV-02, BRV-04			
22	5000	200	3	0,1		INC-01, INC-02, BRV-02, BRV-04	1000 L BRV2	1000 L	
23	5000	1000	3	0,1		INC-01, INC-02, BRV-03, BRV-04			
24	5000	1000	3	0,1		INC-01, INC-02, BRV-03, BRV-04			
25	5000	5000	25	0,1		INC-01, BRV-01, BRV-04, BRV-04			
26	5000	5000	25	0,39		INC-01, BRV-01, BRV-04, BRV-04		1000 L	
27	5000	5000	25	0,39		INC-01, BRV-01, BRV-04, BRV-04			
28	5000	5000	200	3		INC-02, BRV-02, BRV-04, BRV-04			
29	5000	5000	200	3	0,1	INC-01, INC-02, BRV-02, BRV-04, BRV-04			
30	5000	5000	200	3	0,1	INC-01, INC-02, BRV-02, BRV-04, BRV-04	BRV-03	1000 L	500, 500, 500, 2000, 2000, 2000
31	5000	5000	1000	25	0,1	INC-01, BRV-01, BRV-03, BRV-04, BRV-04	BRV-02	1000 L, 1000 L, 1000 L	500, 500, 1000, 2000, 2000

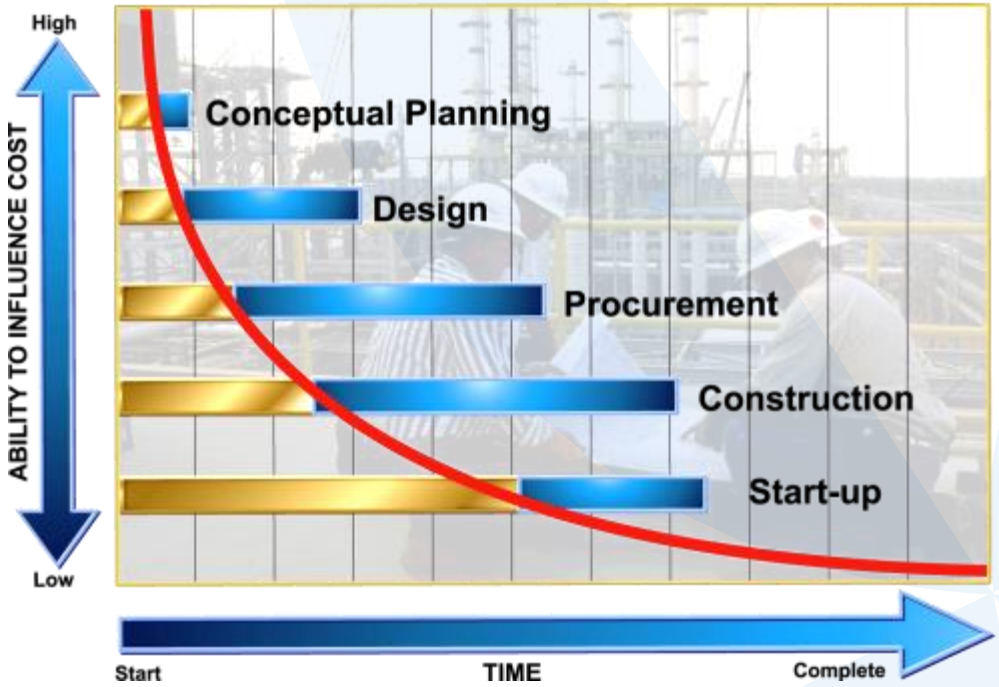
Data presented in table to show which operation is running each day. May also be presented as Gant chart.

Our Process for Delivering Projects

- ***CARE :*** our project delivery process that turns integrated E&C into capital project benefits
  - ***Control cost***
  - ***Accelerate schedule and start-up***
  - ***Reduce risk***
  - ***Enhance value***

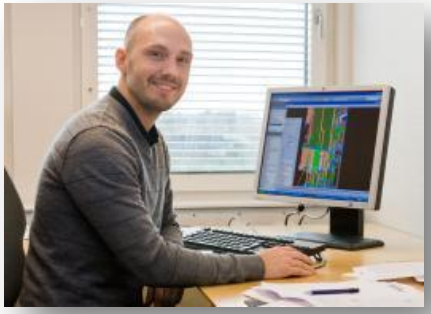
Control Cost

- Make most of the construction and start-up decisions in the conceptual design phase, thus eliminating costly rework
- Collaborate with project team to attain optimal solutions for construction, start-up, and turnover



Control Cost

- Apply strict project controls
  - Strong project management
  - Open communication
  - Control of Key components and equipment within the Telstar Group
  - Subject Mater Expert Equipment Input @ CD phase with ability to optimise Process Cycle times
  - Global Procurement Capability
- Carefully schedule work activities
  - Reduce unscheduled overtime
  - Minimize craft interference
  - For Modular Construction ability to fabricate in controlled environment



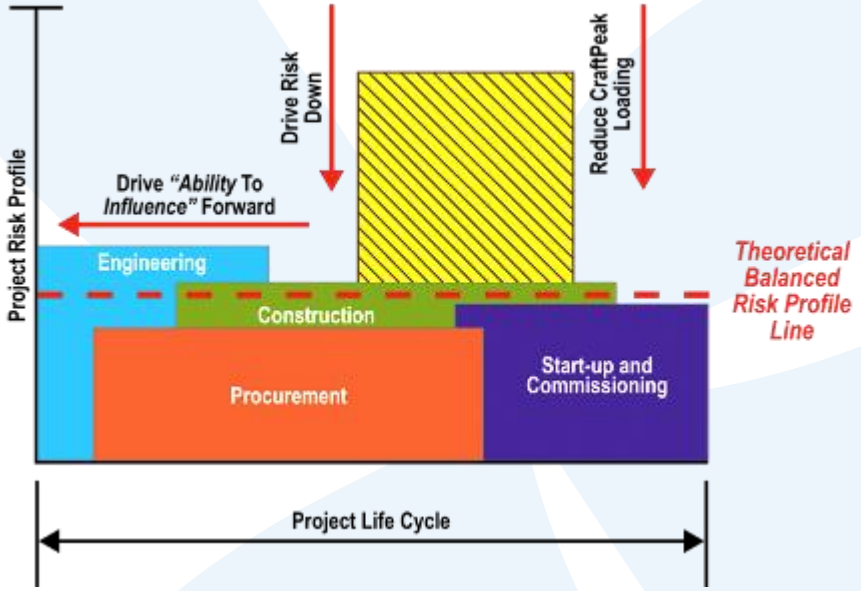
Accelerate Schedule

- Integrate the activities of all disciplines, suppliers, and contractors
  - Ability to include detailed equipment layouts into CD phase for Fill Finish Equipment
  - Lean Validation utilising Engineering documents into Protocol Preparation and Execution
  - Modular Fabrication in our Estonia Workshop

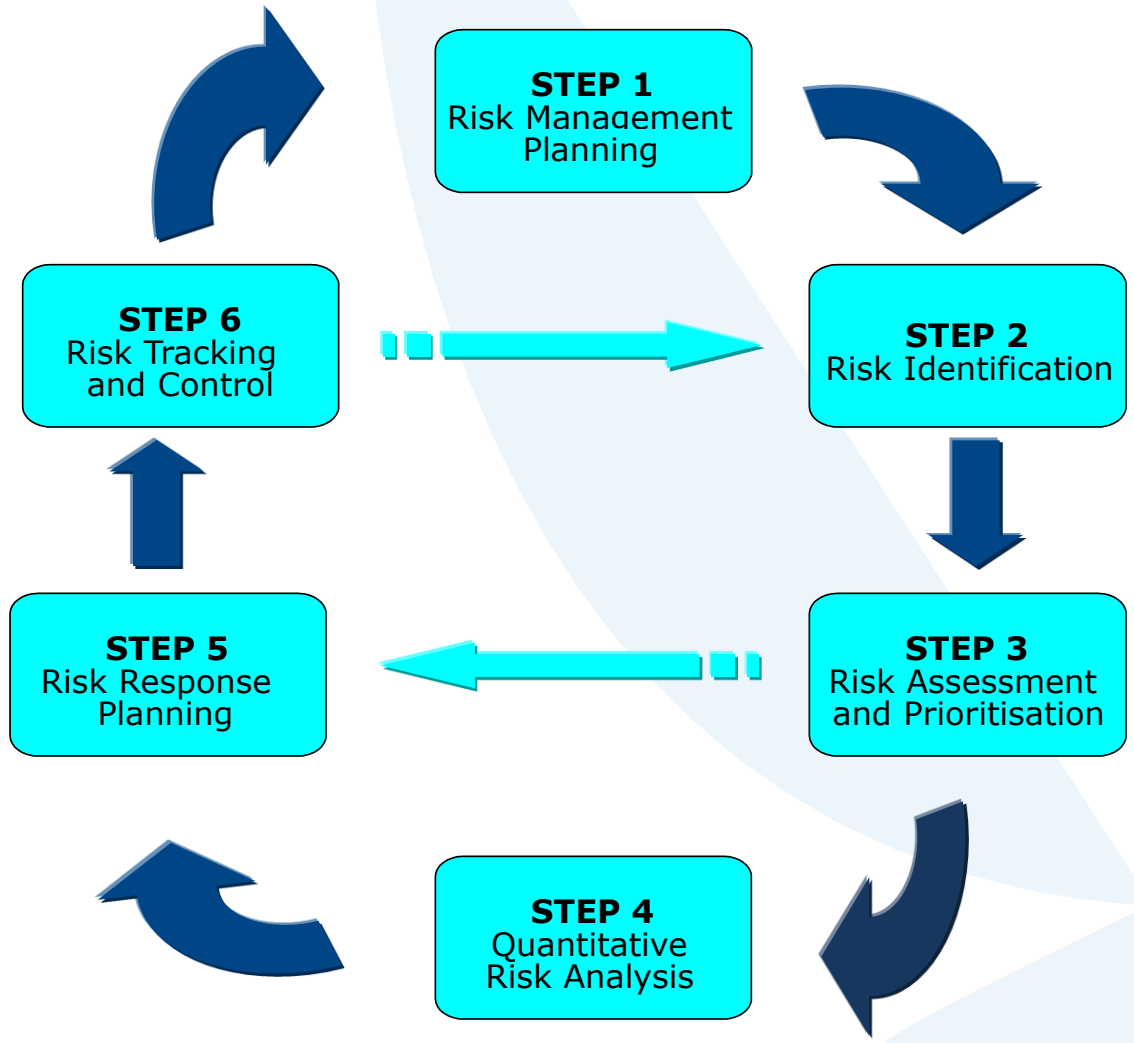
- Benefit from real-time schedule management
  - Concurrent design and construction
  - "Just-in-time" equipment supply
  - Increased workflow efficiency
  - Controlled environment for craft labour in our Estonia workshop

Reduce Risk

- Conduct a thorough risk evaluation during each project step
- CM engaged during project planning
- Continued in alignment sessions throughout the project phases
- Drive down the risk profile with Risk Mitigation Strategy
- Move activities up in the project timeline
- Optimal balance with craft loading and schedule float



Risk Management

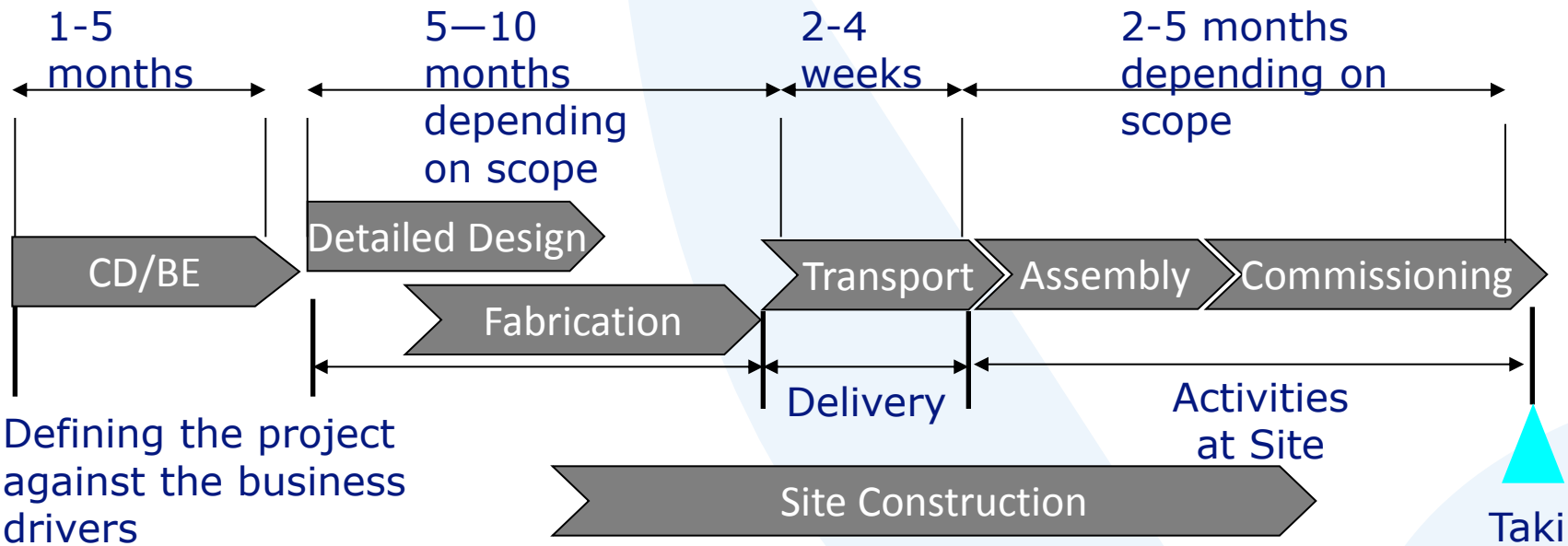


Enhance value

- Direct control of the site safety program
- Modular or Hybrid Solutions for Fast Track Projects and areas of low skilled local labour
- Direct control of the engineering, procurement, and construction planning and scheduling requirements
- Direct control of the subcontractor/vendor quality control and assurance management
- Understanding the Client's Process
- Early Targeting of Commissioning/Start-up, integrated with Lean Validation and Regulatory compliance
- Clear Communication
- A drive for continuous improvement of the effectiveness of resources, methods, relationships, and best practices

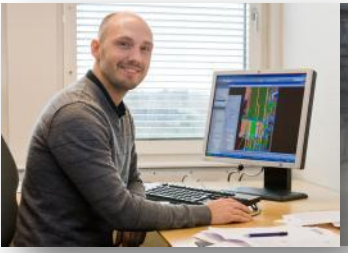
Modular Hybrid Project Execution

A predictable way for execution with risk mitigation



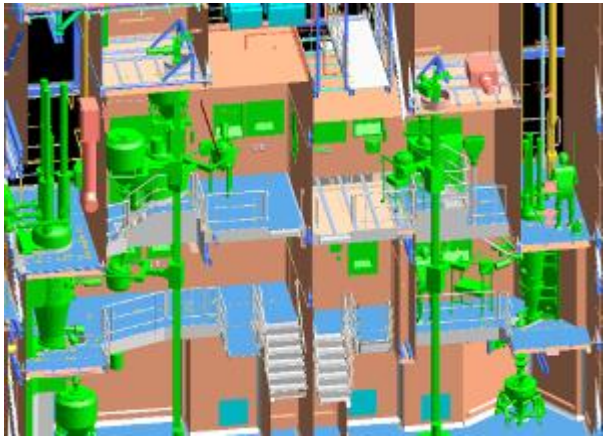
Defining the project against the business drivers

Key to project success!!



Modular Project Execution

Design and Engineering

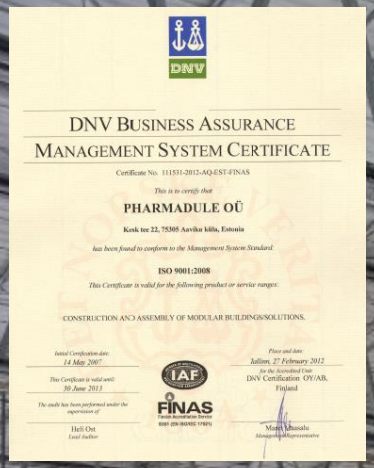


Fabrication

Delivery

Site Erection & Completion

ISO Certified Fabrication



DNV

DNV BUSINESS ASSURANCE

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 111531-2012-AQ-EST-FINAS

This is to certify that

PHARMADULE OÜ

Kesk tee 22, 75305 Aavike küla, Estonia

has been found to conform to the Management System Standard:

ISO 9001:2008

This Certificate is valid for the following product or service ranges:

CONSTRUCTION AND ASSEMBLY OF MODULAR BUILDINGS/SOLUTIONS.

Initial Certification date: 14 May 2007

This Certificate is valid until: 30 June 2013

The audit has been performed under the supervision of:

Heli Ots
Lead Auditor

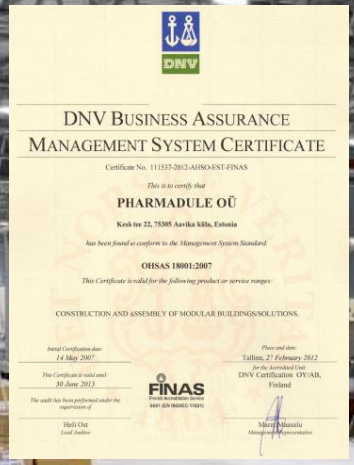
IAF

FINAS
Finnish Accreditation Service
ISO/IEC 17021

Place and date: Tallinn, 27 February 2012

for the Accredited Unit: DNV Certification OY/AB, Finland

Mart Uusalu
Management Representative



DNV

DNV BUSINESS ASSURANCE

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 111537-2012-AHSO-EST-FINAS

This is to certify that

PHARMADULE OÜ

Kesk tee 22, 75305 Aavike küla, Estonia

has been found to conform to the Management System Standard:

OHSAS 18001:2007

This Certificate is valid for the following product or service ranges:

CONSTRUCTION AND ASSEMBLY OF MODULAR BUILDINGS/SOLUTIONS.

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Place and date: Tallinn, 27 February 2012

for the Accredited Unit: DNV Certification OY/AB, Finland

Mart Uusalu
Management Representative

World Class Clean Pipe Weld Workshop

5. A Solution to Today´s Challenges

Today's challenge

- **The Issues**
  - Pharmaceutical companies are demanding projects that are more cost effective, have shorter schedule and higher quality
  - Therefore the Design and Construction Industry Productivity Trends **MUST** continue Towards a Positive & Improving Trend through investment and innovation

Investment Projects in the Future

- **There is a continuous increasing demand for:**
  - Lower cost
  - Shorter Schedule
  - Predictabily and higher quality
  - Flexibility

How Can We Improve?

- **The Options**

There are a Variety of Options and Alternatives utilized to improve project delivery and productivity

- **We have tried different Project Execution Approaches:**
  - o Design, Bid, Build
  - o Engineering, Procurement & Construction Mgt. (EPCM)
  - o Integrated Project Delivery including Qualification
  - o Shell buildings with panels, building modules

How Can We Improve?

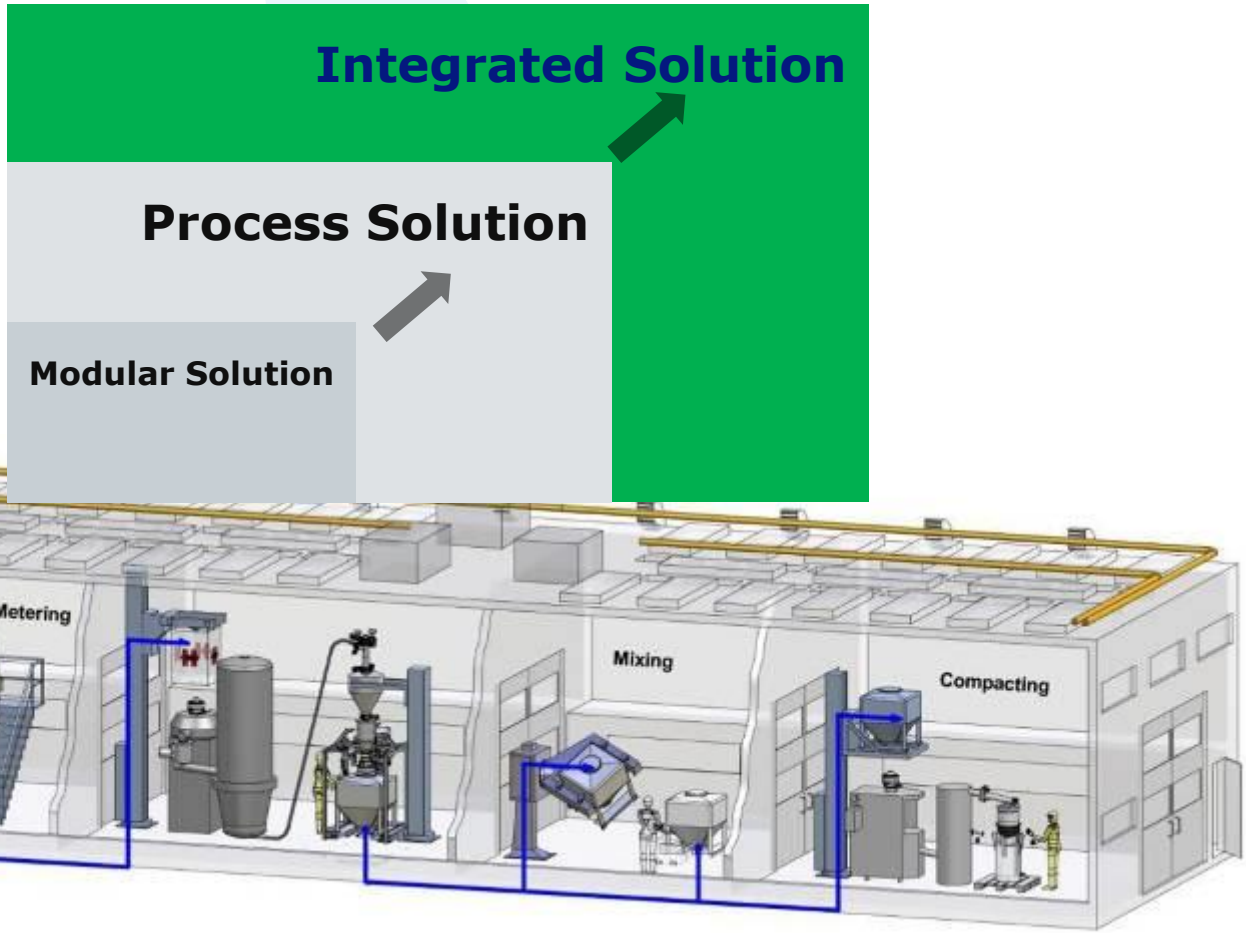
Standardization
with
Innovative Modular Design and Off Site Fabrication

Outlook

- Most Processes and Process Facilities will be Hybrid Modular
- Standardization
- Modular Unit Operations
- Modular Execution is rapidly developing and cost has decreased substantially in the last five years – a trend that will continue

Modular Solutions Changing From…..

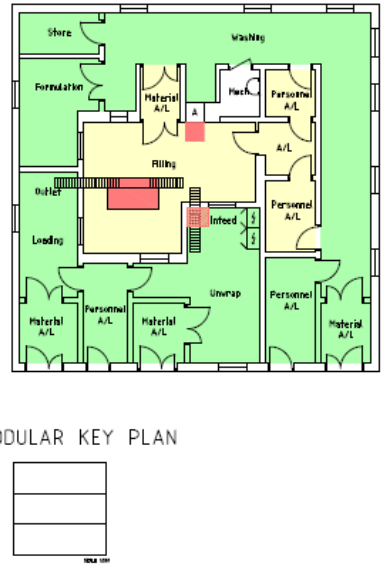
....to Integrated Process Solutions...

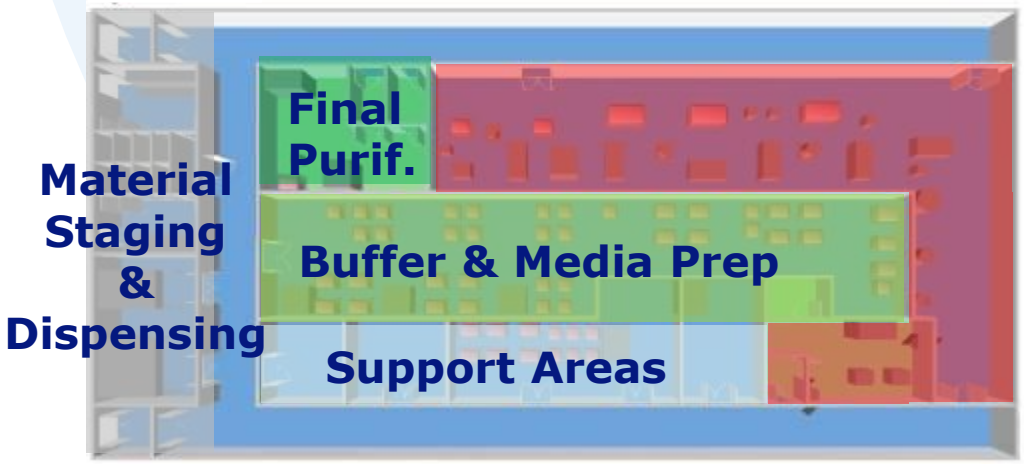


Process planning for a multi-purpose pharmaceutical OSD manufacturing plant

… To Standarization…

- Standard Facilities (Biotech, OSD, Fill Finish)
- Functional Modules





A New Generation Modular Facilities

A New Generation Modular Facilities

Lower cost
Shorter schedule

Predictability and higher quality
Flexibility

Outlook Summary

- ”Modular” has become a buzzword
- Fewer have the experience and resources to execute
- Modularization has proven to be beneficial in many applications
- The Modular Concept is rapidly developing and advancing
  - Modules and Skids for unit operations
  - Standardized Solutions
  - Lower cost
- Modularization is a broad concept – Make sure to Understand What It Means to fit your application

Telstar

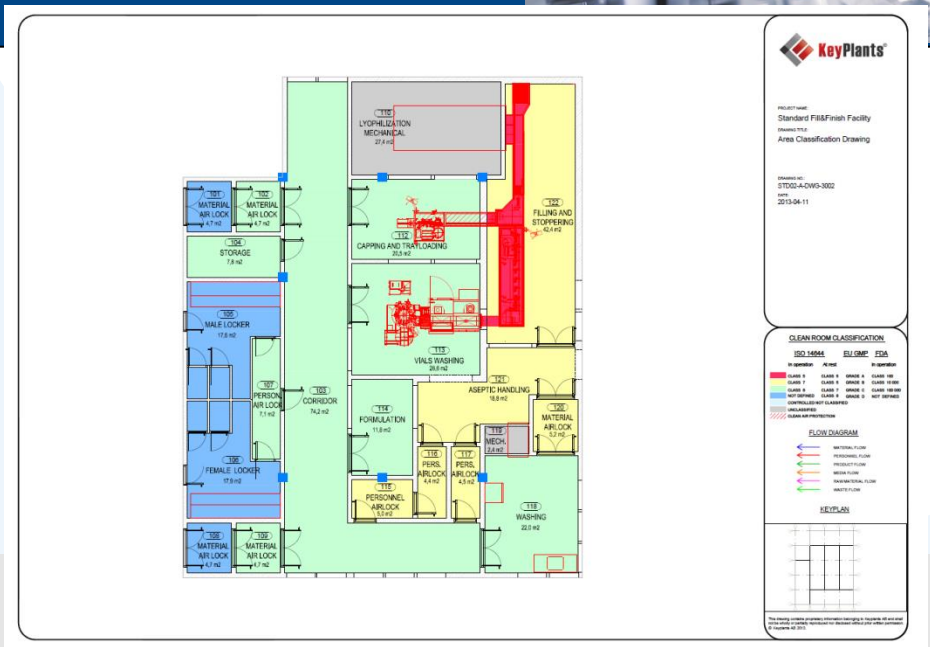
Modular Aseptic Solutions

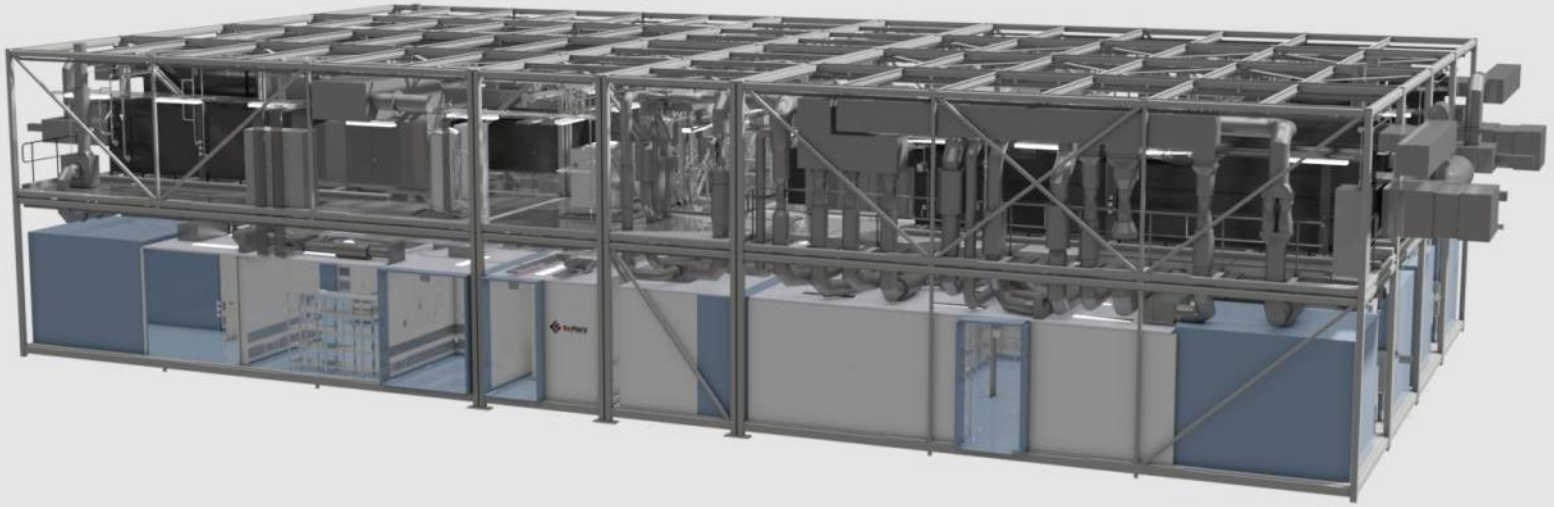
MAS

Facility Battery Limits and Basis of Design

1. Develop a Pre-engineered Modular Aseptic Facility for SVP, aimed at emerging markets, either internal or traditional modules.
2. Facility designed for either Lyophilised Powder or Solutions.
3. Facility to handle either Vials or Syringes; range from 2 to 20ml.
4. Facility to be a single storey design with formulation on ground floor, second line to be easily added without interruption to existing operations.
5. Line speed to be from 200 to 600 vials (2ml) per minute, with either manual or automatic loading of the Lyo.
6. The Facility to be designed for either closed RABs or BI Technology and a Grade C background.
7. Facility battery Limit is the Capper.

MAS – next development step





Facility Construction and Equipment

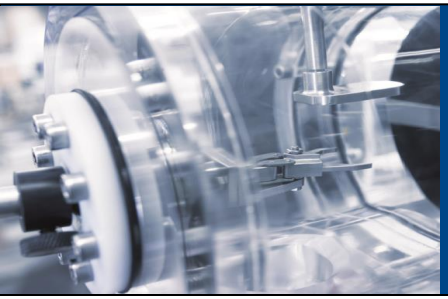
1. Manufacture Modules, initially 100% in Estonia. If Business grows consider manufacture in China and Souththh America (Brazil or Argentina)

2. Use Telstar Equipment in modules
    1. Lyo's.
    2. Autoclaves.
    3. cRABS or Isolators.
    4. WFI & Clean Steam Generation and distribution systems.
    5. Telstar Modular Clean Room Systems).
    6. Azbil EMS

3. Partner for Filling Line (Bosch; Marchesini).

4. Formulation vessels to be manufactured, in Estonia.

5. If Demand exists Fabrication to move to Southh America and China



5. References

References of our Clients
Telstar Group

farma-lepori, s.a.
Grupo Angelini
SANDOZ
sanofi~synthelabo
Answers That Matter.
Lilly
ALK ABELLÓ
MINTLAB
AIR LIQUIDE
Gelos
Roche
Grupo Sabater Análisis
AMGEN
Grupo Uriach
BD
MENARINI
Rubió
Roemmers
SERVIER
CANTABRIA
IPSEN
Innovation for patient care
Grupo Madaus España
MERCK
SALVAT
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NITSA
CASEN Fleet
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gsk
GlaxoSmithKline
VOLPAK
PACKAGING MACHINES
serono
biotech & beyond
ERIOCHEM
Ferrer grupo
Baxter
Zambon
ZAMBON GROUP
ITALFARMACO S.A.
Bayer
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ISDIN
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Lacer
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Labinca
BIOIBERICA
Solvay Pharma
Wyeth
Pierre Fabre
A.S.A.C. PHARMA
Bristol-Myers Squibb Company
ucb Pharma
sigma-tau
PHARMACEUTICALS, INC.
Logista
MAVER
Schering-Plough
Grupo Vita
PROPHARMAL
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CASASCO
LPA
Laboratoire Pharmaceutique Algérien
GMB
Industrias GMB, s.a.

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