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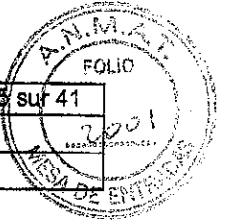
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**APPENDIX 4****NO CONTRACT MANUFACTURERS****CONTRACT LABORATORIES:**

QUALITY ASSISTANCE Technoparc de Thudinie 2 B-6536 Donstiennes	+32 (0)71 53 47 81 +32 (0)71 53 42 16	Certified Lab
SGS- LAB SIMON Vieux Chemin du Poète 10 B-1301 Wavre	+32 (0)10 42 11 11 +32 (0)10 42 11 00	Certified Lab
LABO THERMIBEL	Tél : 064-67.15.00. Fax : 064-67.15.12.	Certified Lab

**CONTRACT COLD TRANSPORT:****MOVIANTO/ Dirk Raes**

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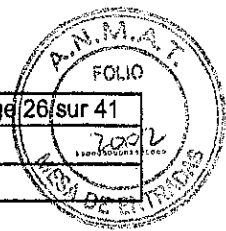
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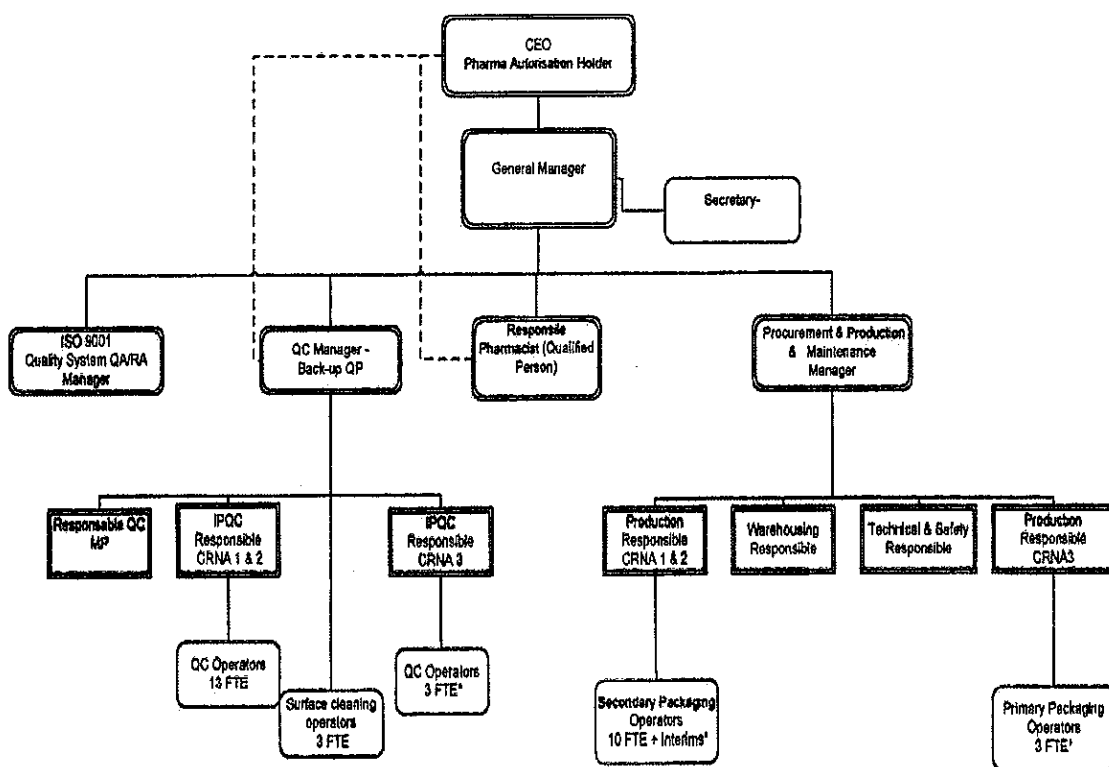
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**ATTACHMENT 5  
Organisation chart**



\* depending of the activity

DES\_034\_organigramme CRNA 123 v 2.0

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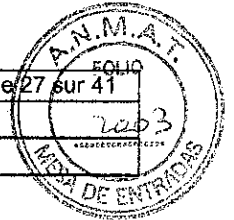
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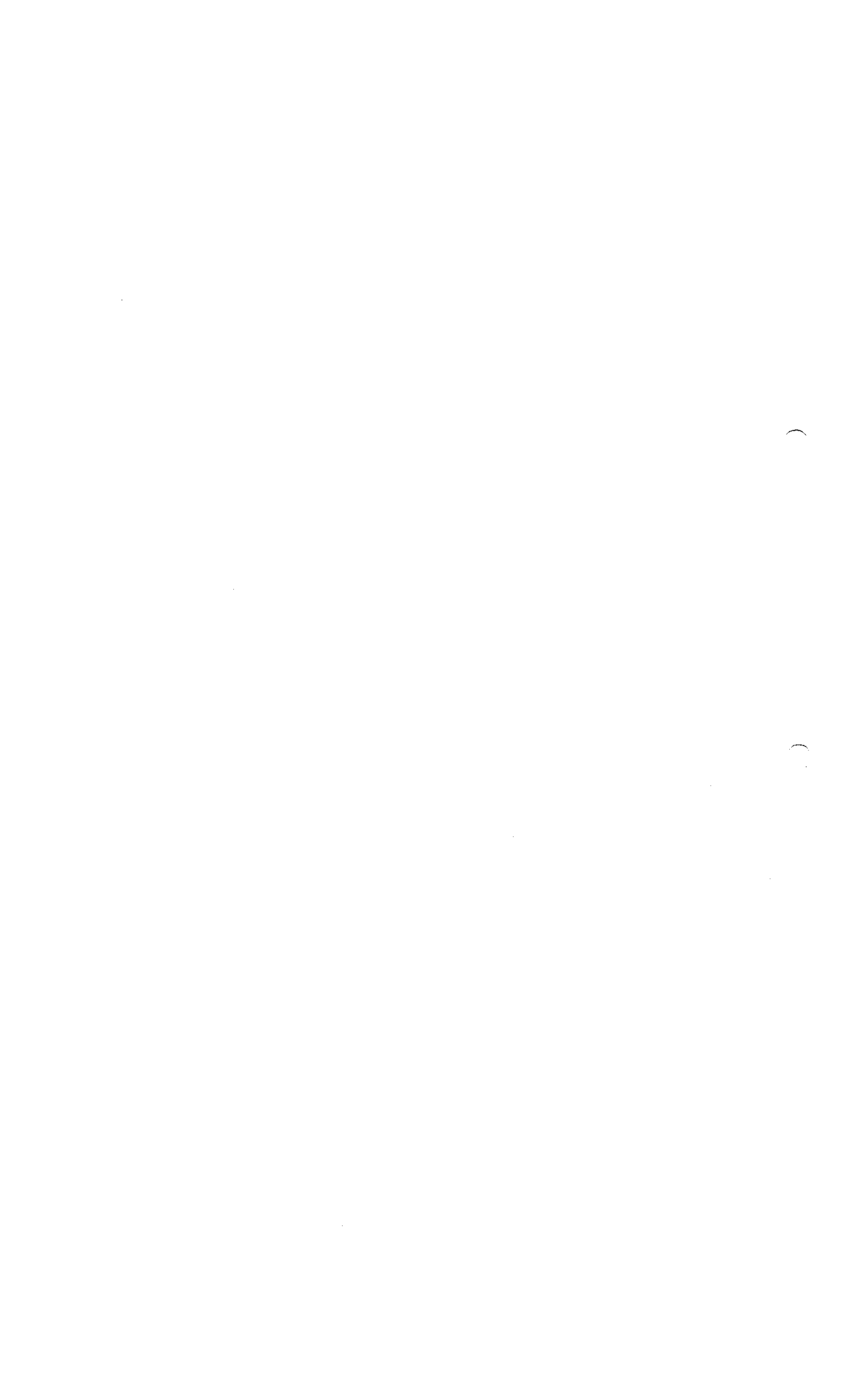
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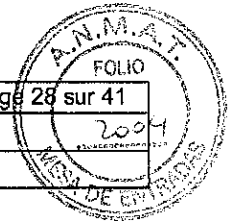
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**ATTACHMENT (continued)**

Key functions	Qualification	Incumbent
<b>CRNA Employees</b>		
CEO Authorisation Holder	Industrial Engineer CEO experience	Jean Martin
General Manager	Engineer	Bernard Renguet
Qualified Person/QC Manager	Industrial pharmacist With experience as QP	Henri Dedeken
Senior QA Systems Manager ISO 9001 Representative Regulatory Affairs	Industrial pharmacist IRCA Certified Auditor With experience	Kathy Dekeyser
QC Manager/Back-up QP	Industrial pharmacist With experience as QP	Thérèse Braems
Procurement & Stock & Production & Maintenance Manager	Engineer	Bernard Renguet
Production Responsible CRNA 1&2	Graduate A1 clinical biology	Estérina Chiaravalle
Production Responsible CRNA 3	Industrial Pharmacist With experience in QC lab and production	Henri Dedeken
Responsible In Process Control Primary	Graduate A2	To be defined
QC Responsible	Graduate A2	Nathalie Busignies
Responsible In Process Control Secondary	Graduate A2	Nathalie Busignies Nathalie Mabilote
Technical & Safety Responsible	Electromecanics	Erwin Hirsoux
Warehousing Responsible	Secondary school- College level	Antal Indi/G. Defamie
Secretary	Secretary	Virginie Conte
Office administrator	Graduate Marketing	Bastien Leonard
<b>CRNA Workers</b>		
QC Operators	Secondary school- College level	
Surface cleaning operators	Primary school	





**ATTACHMENT  
Service providers**

Name and address of the company	Telephone and fax number	Area of expertise	Contract
ABC Engineering route du Vin 60 L-5405 Bech-Kleinmacher Luxembourg	+32 (0)475 96 17 93 +35 226 67 12 28	Engineering consultancy	X
ADHESIA rue Puissant 15 B- 6000 Charleroi	+32 (0)71.733.417 +32 (0)71.733.415	Personnel: Prevention and Protection at work	X
AIRCONSULT ENGINEERING rue des Frères Wright 29 6041 Gosselies-aéropôle	+32 (0)71.254.030 +32 (0)71.254.031	Engineering Consultancy	X
ANALIS Zoning Industriel Rhines rue de Néverlée 11 5020 Suarlee	+32 (0) 81 25 50 73 +32 (0) 81 25 50 69	Weighing scales maintenance	X
AXIMA Z.A.E. du Faubourg rue du Chénia 1 B-7170 Manage	+32 (0) 64.51.62.11 +32 (0) 64.54.98.02	Preventive maintenance of air conditioning system HVAC CRNA 1, 2, 3 and cold rooms	X
BIK Boulevard Tirou 17 6000 Charleroi	+32 (0) 71 54 92 70 +32 (0) 71 54 92 73	Interim Personnel	X
CCS BE Helststraat 51-10 2630 Aartselaar	+32 (0) 3 877 60 30 +32 (0) 3 877 57 44	Cleanroom consumables	Supplier
CMI avenue de Ramelot 3 B-1480 Saintes-Tubize	+32 (0)2.531.11.21 +32 (0)2.531.11.29	Qualification of clean rooms and refrigerated storage rooms	X
CVB Recycling radiatorenstraat 51 B-1800 Vilvoorde	+32 (0) 2.252 55 84 +32 (0) 2.252 45 55	Certified destruction of unused printed packaging materials	X
DAOUST avenue Paul Pastur 65/67 6001 Marcinelle	+32 (0) 71 47 95 75 +32 (0) 71 47 95 97	Interim Personnel	X
DRUART Avenue Léopold III, 31 7134 PERONNES-LEZ-BINCHE	+32(0)64 31 09 20 +32(0)64 31 09 21	Heating system warehouse (preventive maintenance)	X
ESC rue de la Fusée 64 B-1130 Bruxelles	+32 (0) 2.726. 02.70 +32 (0) 2.726. 02.10	Monitoring alarms 24h/24h	X
EUROWATER Industriezone Eke Rozenstraat 7 9810 Nazareth-Eke	+32 (0) 9 228 18 61 +32 (0) 9 228 15 03	Maintenance and sanitation demineralised water installation	X
GOM chaussée de Louvain, 817 B-5020 Champion	+32 (0)81 327 777 +32 (0)81 312 571	Cleaning company	X

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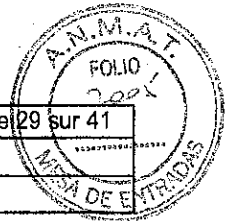
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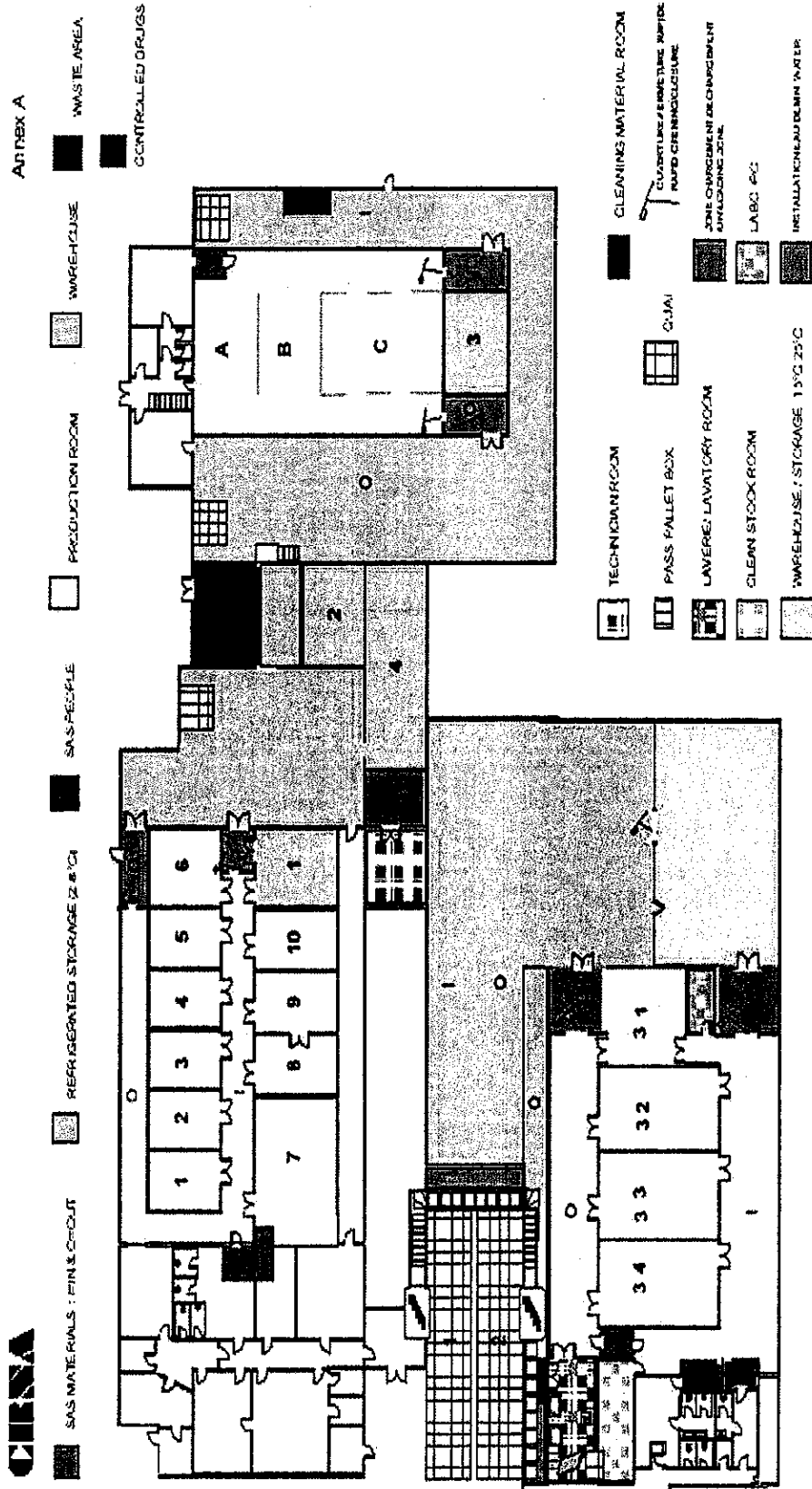


HYGIENE CONTROL avenue J. César 7 B-1150 Bruxelles	+32 (0) 2.770.36.14 +32 (0) 2.770.89.35	Pest control	X
INITIAL TEXTILES Zoning Industriel B-6220 Heppignies	+32 (0) 71 34 19 97 +32 (0) 71 34 17 23	Cleanroom gowning and cleaning of clothes	X
IPM (Intégration Pharmaceutique Modulaire) ZI Le Treil – Fr-47520 Le Passage d'Agen	+33 (0)553 68 47 52 Technician: +33 6 60 58 55 75	Service for thermoforming machine (preventive maintenance)	X
KONE BELGIUM avenue Jean Mermoz 29A B-6041 Gosselies (Charleroi)	+32 (0) 71 36 35 34 +32 (0) 71 47 20 34	Maintenance rolling doors	X
MECOTEC avenue Newton 9 B-1300 Wavre	+32 (0) 10 65 41 11 +32 (0) 10 65 41 12	Monitoring system T° cold rooms and HVAC	X
MOVIANTO Belgium Dirk Raes Moerstraat 48-50 B-9031 Gent	+32 (0)53 83 18 12 +32 (0)53 84 15 09	Refrigerated transport (2°C-8°C)	X
MULTIVAC Maanstraat 23 B-2800 Mechelen	+32 (0)15.56.95.10 +32 (0)15.56.95.01	Service for Multivac thermoforming machine (preventive maintenance)	X
QUALITY ASSISTANCE Technoparc de Thudinie 2 B-6536 Donstiennes	+32 (0)71 53 47 81 +32 (0)71 53 42 16	Certified Lab	X
SGS- LAB SIMON Vieux Chemin du Poète 10 B-1301 Wavre	+32 (0)10 42 11 11 +32 (0) 10 42 11 00	Certified Lab	X
SITA WALLONIE SA RUE DE L'AVENIR 22 4460 GRACE-HOLLOGNE	+32(0)4 247 31 31 +32(0)4 247 31 47	Certified company for destruction of pharmaceutical products	At each supply
START PEOPLE chaussée de Charleroi 590 6220 FLEURUS	+32 (0) 71 81 31 91 +32 (0) 71 81 37 98	Interim Personnel	X
TEMPO TEAM chaussée de Châtelet 8 6000 Gilly	+32 (0) 71 28 04 90 +32 (0) 71 48 91 79	Interim Personnel	X
THE BELGIAN Slozenstraat 66 A, B-1861 Meise (Wolvertem)	+32 (0) 52 31 59 60 +32 (0) 52 31 59 69	Security Systems Fire Protection	X
THERMIBEL ZI PAVE DU ROEULX 1 7110 - LA LOUVIERE STREPY- BRACQUEGNIES.	Tél : 064-67.15.00. Fax : 064-67.15.12.	QC control TempTales and Freeze-tags	X
TRANS'O FLEX (MIT) Breimheidslaan 10 2300 Turnhout	+32 (0)14 42 60 51 +32 (0)14 42 55 80	Transport	Not active
VAN DAMME rue Chant des Oiseaux 15 B-1470 Baisy Thy	+32 (0)71.88.00.00 +32 (0)71.88.00.09	Electricity generator (Back-up electricity)	X
YOKOGAWA Minervastraat 16 B-1930 Zaventem	+32 (0) 2.719.55.11 +32 (0) 2.725.34.99 +32 (0) 2.719.55.63	Monitoring system T° cold rooms and HVAC	X





**ATTACHMENT: Site Plan CRNA**

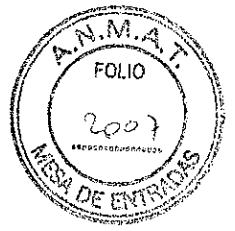



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<b>CRNA SITE MASTER FILE</b>				

**ATTACHMENT: Room classification in CRNA 3**

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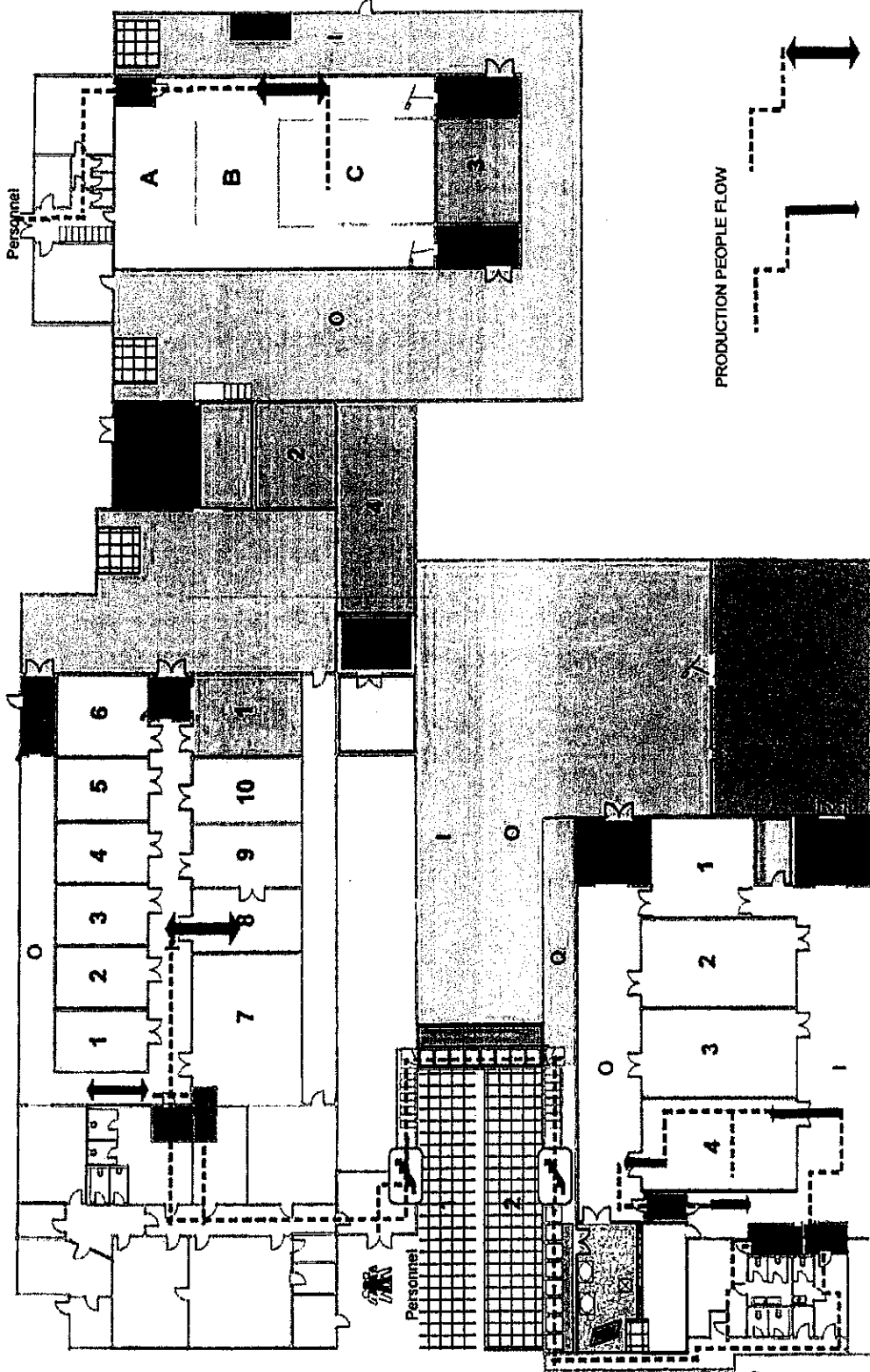
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# FLOW PRODUCTION PEOPLE

- SAS MATERIALS: IN & OUT
- REFRIGERATED STORAGE (2-8°C)
- SAS PEOPLE
- CLEAN ROOM CLASS ISO 8
- WAREHOUSE
- REJECTS AREA
- CONTROLLED DRUGS



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**ATTACHMENT : Flow of personnel**

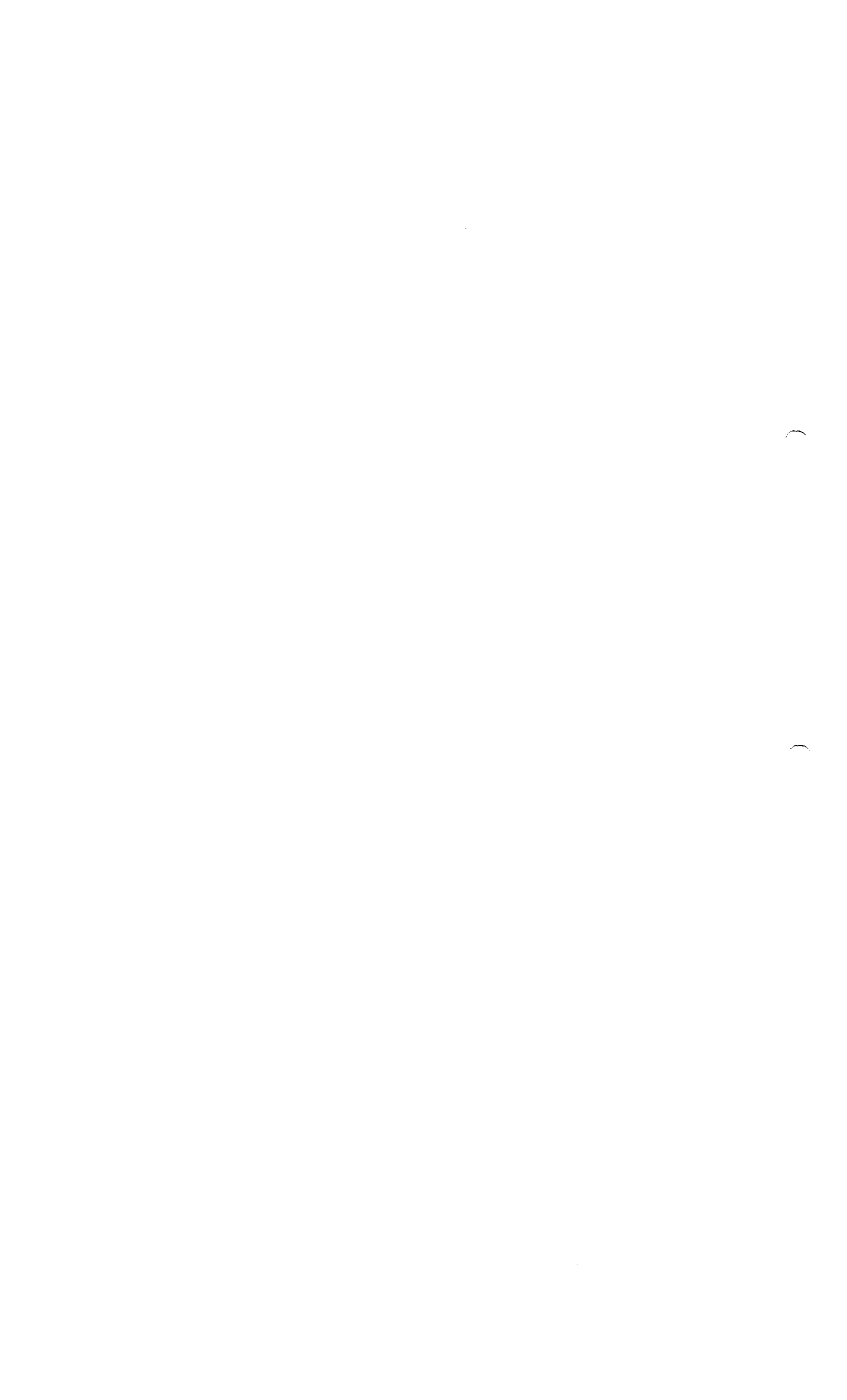
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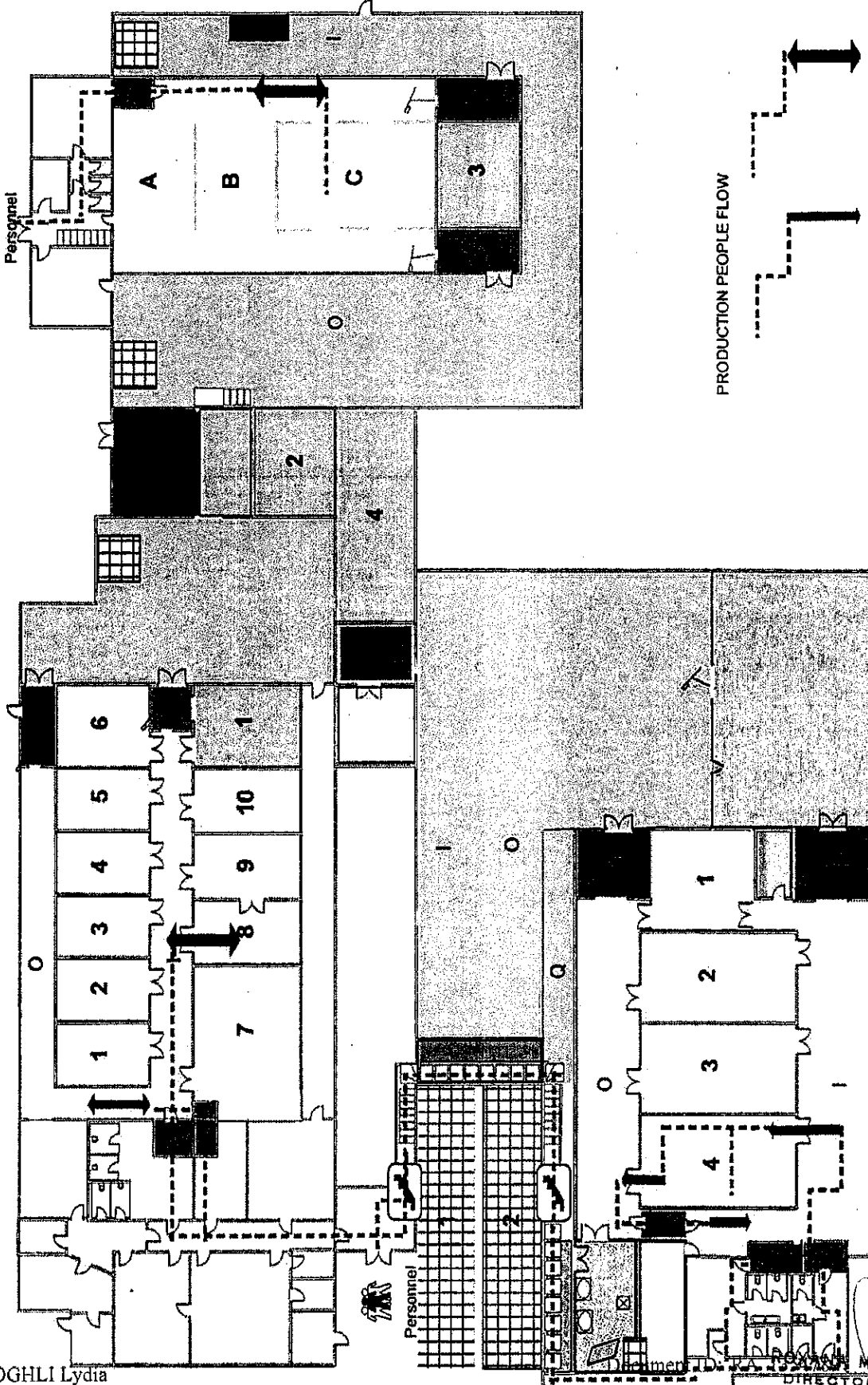
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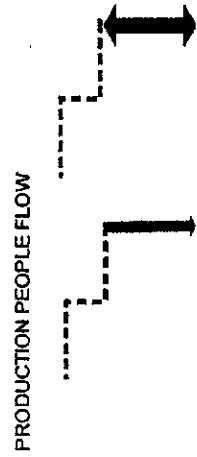


# FLOW PRODUCTION PEOPLE

- SAS MATERIALS : IN & O-OUT
- REFRIGERATED STORAGE (2-8°C)
- CLEAN ROOM CLASS ISO 8
- SAS PEOPLE
- WAREHOUSE
- REJECTS AREA
- CONTROLLED DRUGS



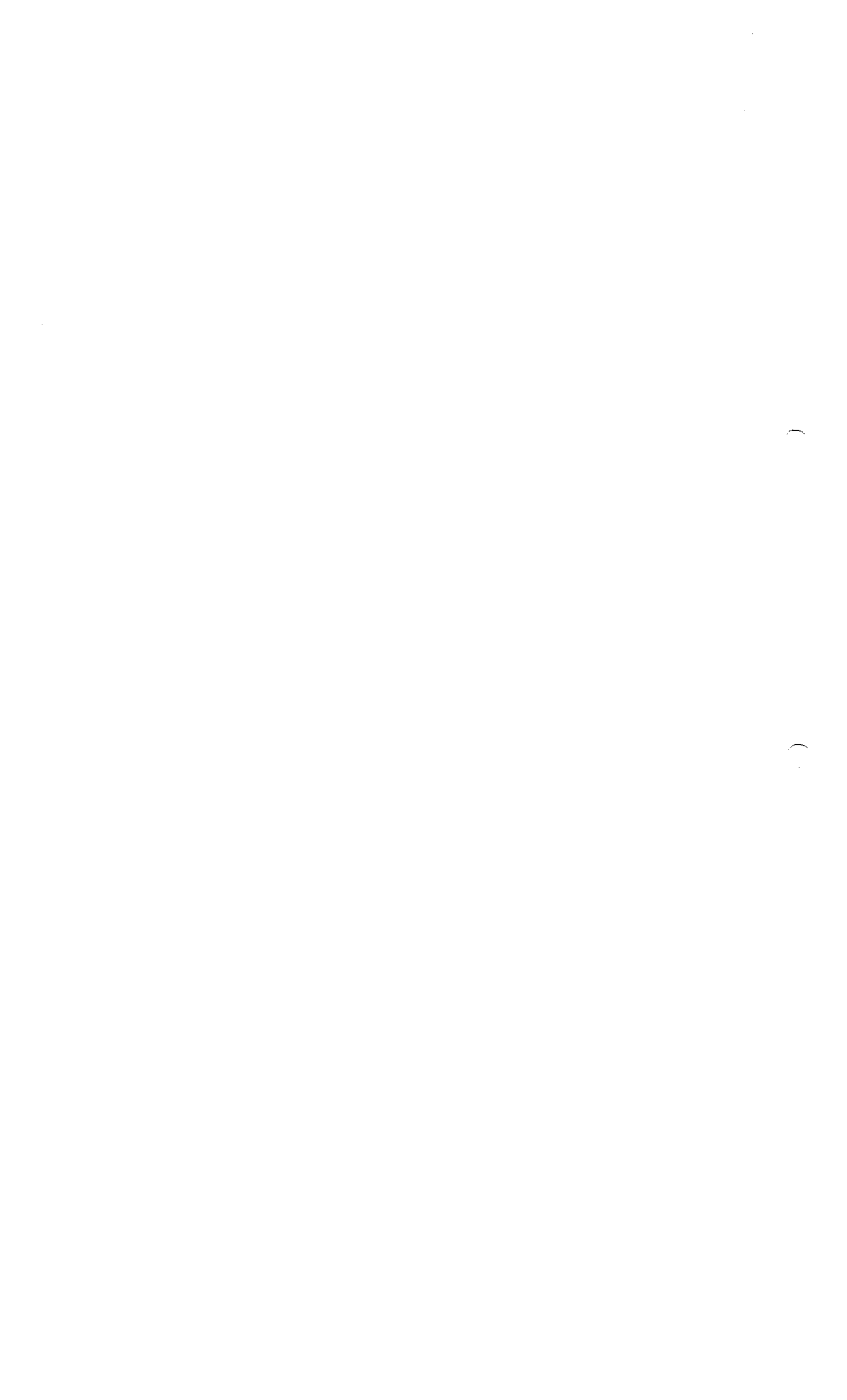
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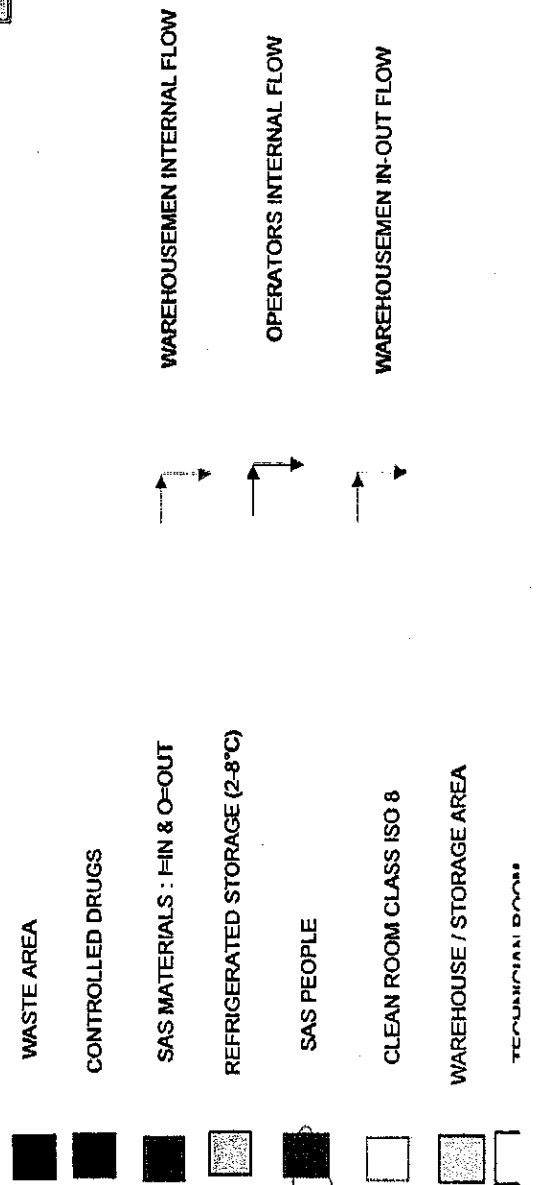
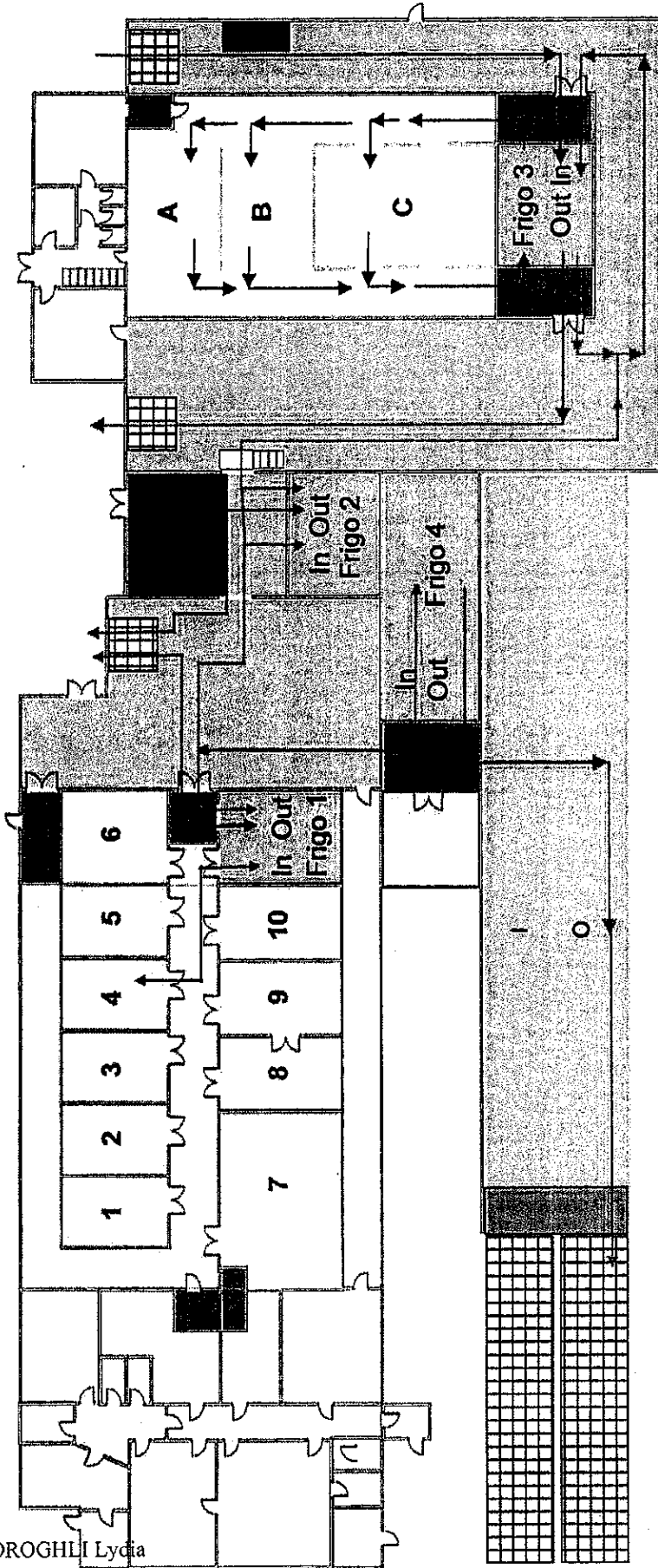
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**ATTACHMENT : Materials Flow in CRNA 2**

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<b>CRNA SITE MASTER FILE</b>				

**ATTACHMENT CRNA 2 zone C**

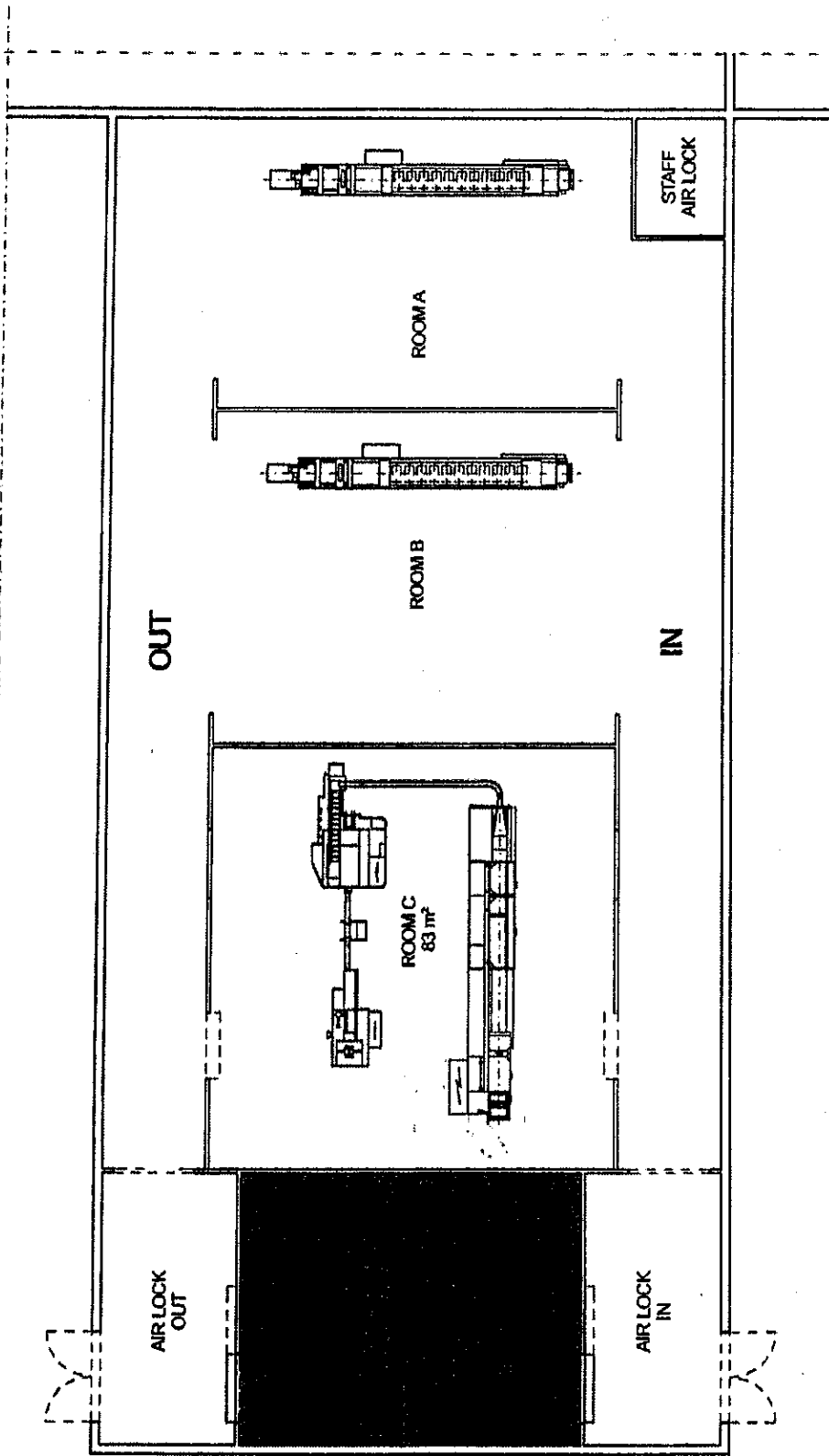
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Z-1 Avenue d'Heppinnes  
6220 FLEURUS  
Tel.: 32 (71) 37 60 85  
Fax: 32 (71) 37 40 86

P H A R M A

Title: Project PMVH GSK Bio WARE

Scale: 1/100 Designer: HIE Date: 12/10/2011

Index Date

1.0 12/10/2011

Modifications

General overview of production

- LEGEND**
- Lockable access to room C
  - Lockable access to cold room

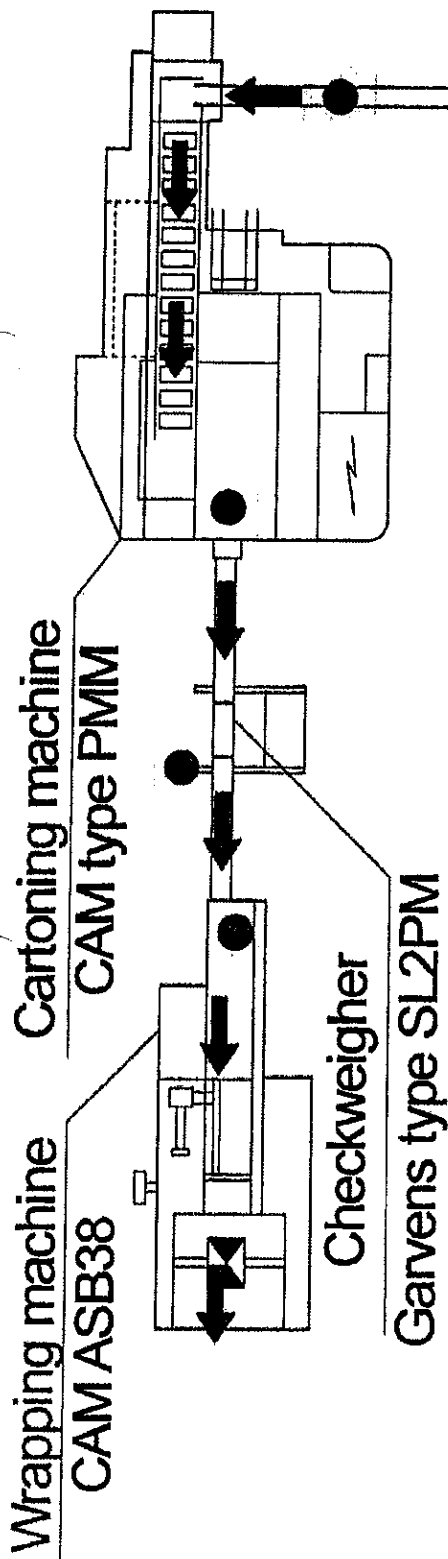


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**LEGEND**

- Manual feeding of the blisters
- Reject station: blisters rejected by the camera or the thermoforming machine.
- Reject station: Blisters rejected by the cartoning machine.
- Reject station: boxes rejected by the OCV or the cartoning machine
- Reject station: boxes rejected by the checkweigher.
- Reject station: boxes rejected by the wrapping machine.

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Z-1 Avenue of Heptagones  
 6220 FLEURUS  
 Tel: 32 (71) 37 60 85  
 Fax: 32 (71) 37 40 86

Title: Project PMVH GSK Bio WAVRE

Scale: 1/100 Designer: HIE Date: 17/10/2011

Index Date Modifications

1.0 17/10/2011

Line floor Project



