



ONCOLOGICAL PROJECTS REFERENCES



We *Process*, *Build*, *Engineer*



www.pbe-expert.com

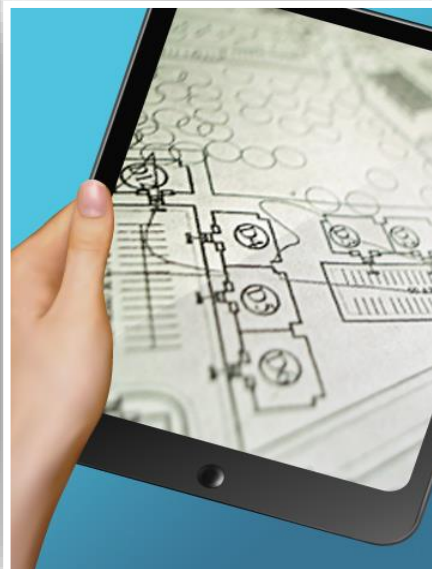
We *Process*, *Build*, *Engineer*

PBE EXPERT INC

FABRICATION



TECHNOLOGY



ENGINEERING



CONSTRUCTION





We **P**rocess, **B**uild, **E**ngineer



ONCOLOGICAL PROJECTS REFERENCES



INJECTABLES & ONCOLOGICAL CONTAINMENT EQUIPMENT SUPPLIERS

Turnkey Project / Engineering & Construction

General Contractor

Civil, Mechanical, Electrical Engineering, Architects

PBE, Pharma Bio Expert

Layout, cGMP Audit Compliance, Sanitary Design of Process
Equipment, Clean Utilities & Pharmaceutical Systems

www.pbe-expert.com

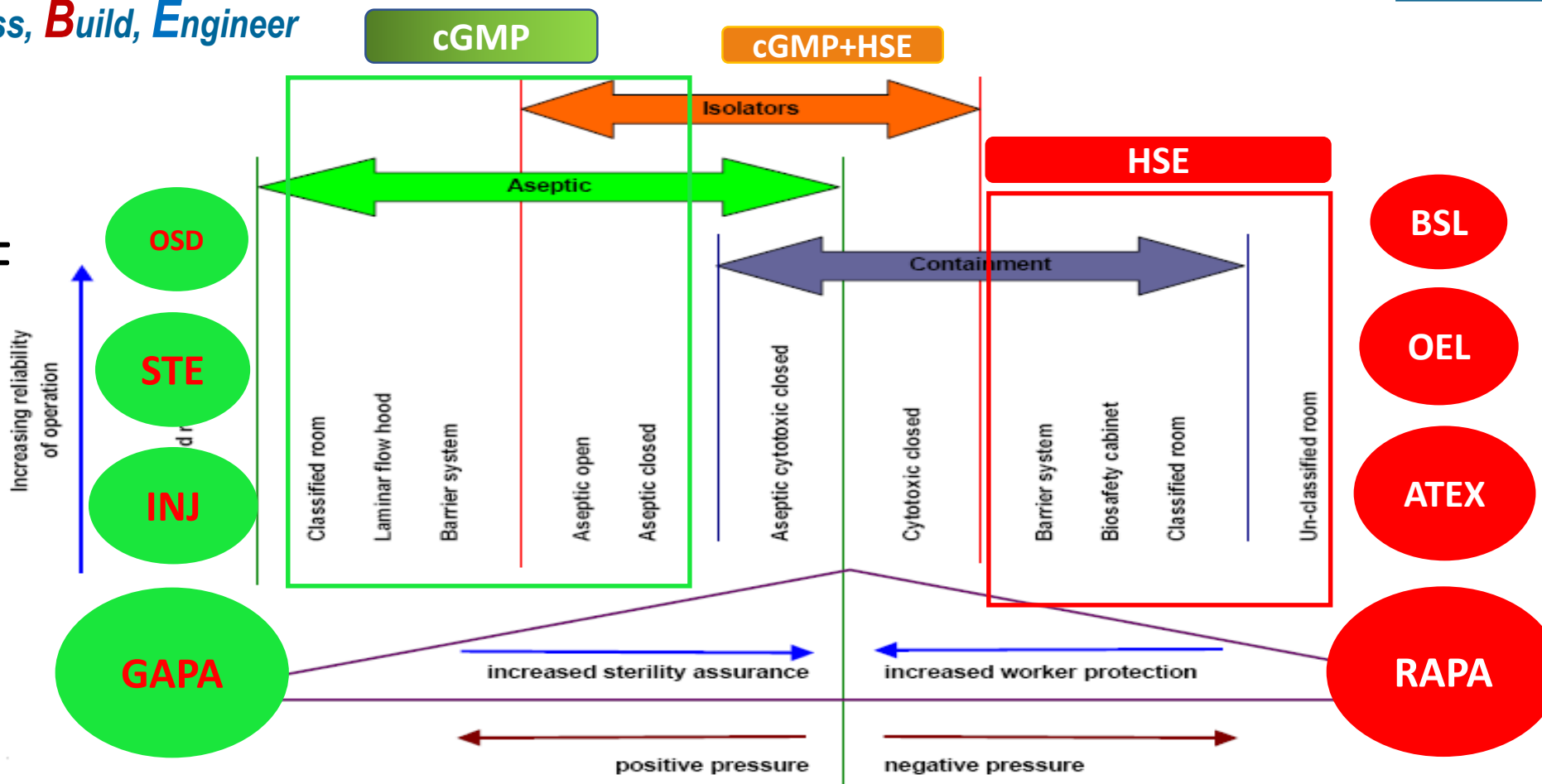
ONCOLOGICAL PROJECTS REFERENCES

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We *Process*, *Build*, *Engineer*

Aseptic F&F
Facility
with
Specific
Design

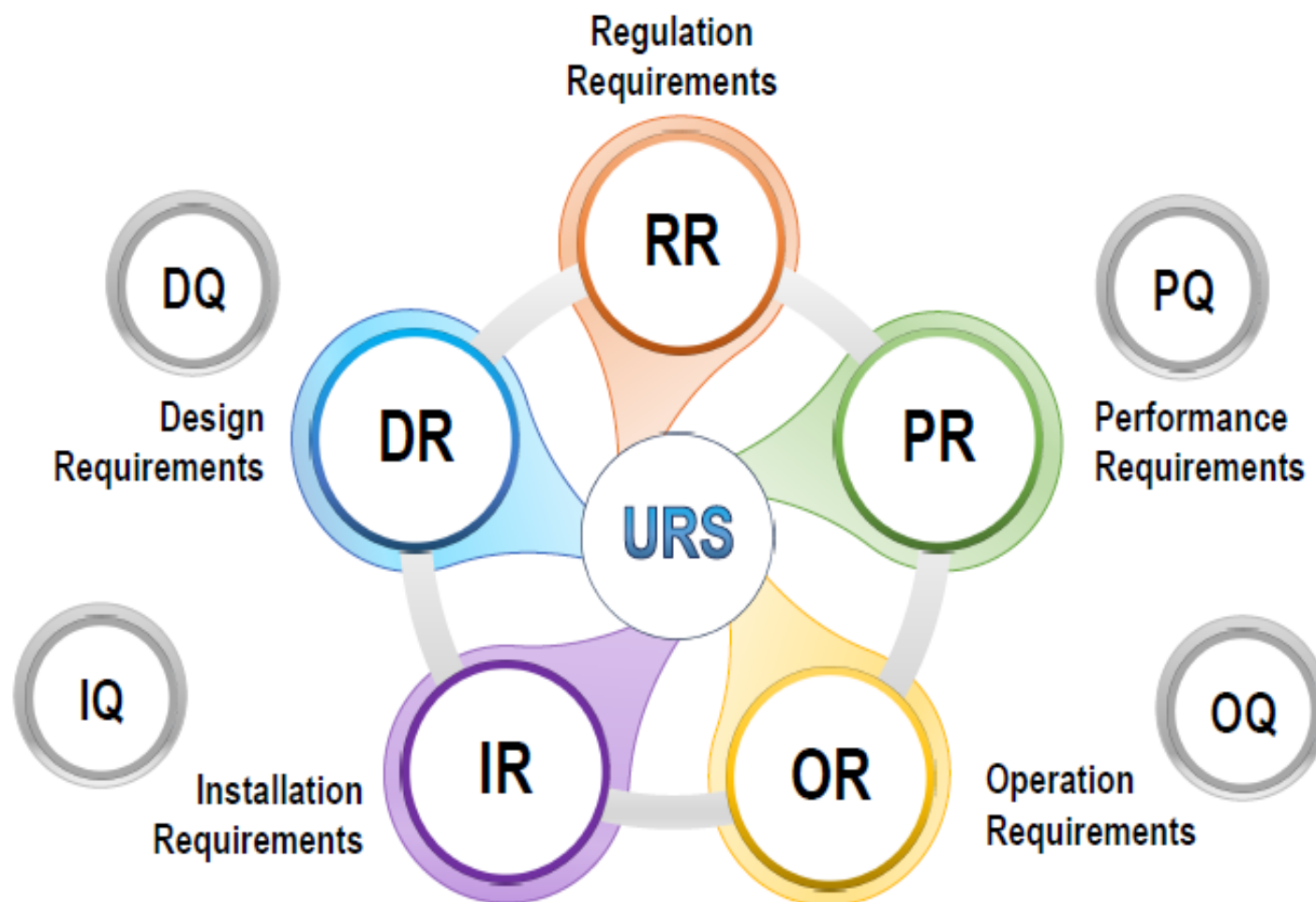


We *P*rocess, *B*uild, *E*ngineer

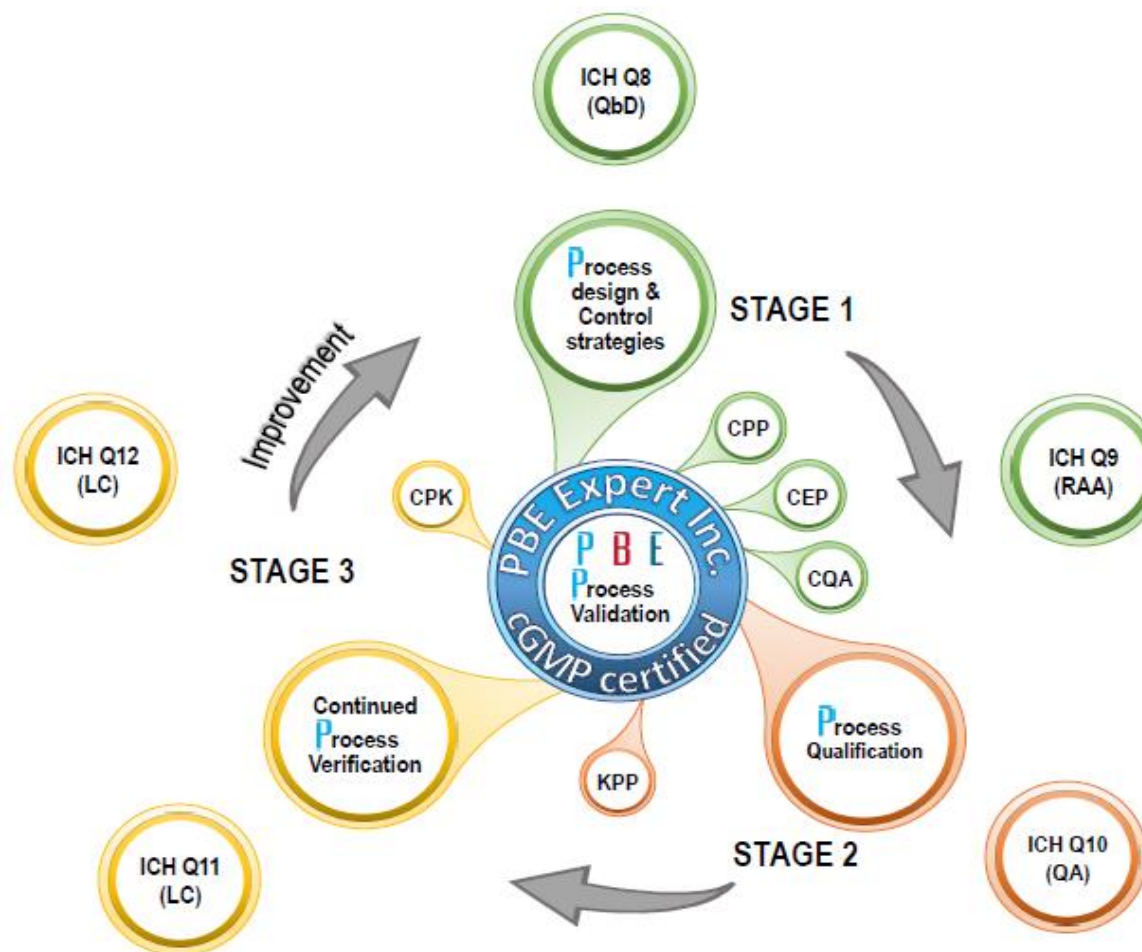
8PURS (User Requirement Specifications) x 100



CPP, URS, Qualification ?



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We *Process*, *Build*, *Engineer*

M/S. PURLAB
Oran, Algeria, 2018-2021
(EPCMV)
FACILITY: OSD Oncological, OEL5

- cGMP Compliance Audit
- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Pharmaceutical Systems Design
- Installation & Commissioning
- Validation & VMP

➤ EMA APPROVED

M/S. IPSEN BEAUFOUR
Dreux, France, 2005-2006

FACILITY: ONCO OSD OEL5

- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Pharmaceutical Systems Design

➤ FDA & EMA APPROVED

M/S. PHARMAGHREB
Tunis, Tunisia, 2015-2016

FACILITY: ONCOLOGICAL ORAL
SOLID DOSAGE OE5

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Basic Engineering BOD
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Containment Technology

➤ FDA & EMA APPROVED

M/S. ENDOCEUTICS Montreal,
Canada, 2016-2018 FACILITY:
VAGINAL OVULES, OEL3
(EPCMV)

- cGMP Compliance Audit
- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Installation & Commissioning
- Validation & VMP

➤ FDA & EMA APPROVED

We *Process*, *Build*, *Engineer*

M/S. PHARMAGHREB
Tunis, Tunisia, 2015-2016

**FACILITY: HORMONAL SOLID
DOSAGE, OEL5**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning

M/S. MEDICEF - HIKMA
Tunis, Tunisia, 2015

**FACILITY : CEPHALOSPORINE
BETA-LACTAME ORAL SOLID
DOSAGE OEL3**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Risk Analysis & Preventive
Actions
- Audit
- Training

M/S. MEDIS
Tunis, Tunisia, 2014

**FACILITY: OSD FORM
ONCOLOGICAL OEL5**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Audit & Compliance Review
- Gap & Risk Analysis &
Preventive Actions
- Layout Design Re-Engineering
- Containment Technology
- FAT

M/S. CONFIDENTIAL
Tunisia, 2013

**FACILITY: OSD FORM & BETA-
LACTAM**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning

We *Process*, *Build*, *Engineer*

M/S. MEDIS Laboratories
Nabeul, Tunisia, 2014-2015

FACILITY: INJECTABLE &
ONCOLOGICAL OEL5

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Audit & Compliance Review
- Gap & Risk Analysis & Preventive Actions
- Layout Design Re-Engineering
- Containment Technology
- FAT

M/S. IPSEN BEAUFOUR
Dreux, France, 2005-2008

FACILITY: ONCO INJECTABLE OEL4

- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Pharmaceutical Systems Design
- Installation & Commissioning
- SOP
- Validation
- FDA & EMA APPROVED

/S. PIERRE FABRE
Pau, France, 2007

FACILITY : STERILE OEL5

- Conceptual Design
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Pharmaceutical Systems Design
- Installation & Commissioning
- SOP
- Validation

M/S. Denis Giroux Laboratories
Montreal, Canada, 2005

FACILITY: F&F SV-USP797-HP-OEL5

- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Process Eqpmt / Engineering
- Construction Management
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Installation & Commissioning
- SOP
- Validation
- HEALTH CANADA APPROVED

We *Process*, *Build*, *Engineer*

M/S. APTALIS
Montreal, Canada, 2014-2015

**FACILITY: SUPPOSITORY
FORM OEL5**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Gap Analysis & Preventive Actions GAPA
- Risk Analysis & Preventive Actions RAPA
- Audit & Compliance Revue
- Design Review
- Containment Technology

M/S. CONFIDENTIAL
Tunisia, 2013

**FACILITY: OSD FORM & BETA-
LACTAM, OEL3**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- Containment Technology
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design



We *P*rocess, *B*uild, *E*ngineer

ONCOLOGICAL PROJECTS REFERENCES



Thanks !



PBE, Pharma Bio Expert Inc
PBE, your c-GMP Regulation
& Engineering Compliance Partner

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(Canada) : O+1.450-600-0790
M.+1.514-616-2692

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pbe@pbe-expert.com

Canada

www.pbe-expert.com



HEALTH CANADA
EXPERT
SANTÉ CANADA
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ONCOLOGICAL PROJECTS REFERENCES



We *Process*, *Build*, *Engineer*

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INGÉNIERIE _ ETUDES TECHNIQUES _ ESSAI ET CONTRÔLE _ QUALIFICATION _ MÉTROLOGIE

We *Process*, *Build*, *Engineer*

M/S. PURLAB

Oran, Algeria, 2018-2021
(EPCMV)

FACILITY: OSD Oncological, OEL5

- cGMP Compliance Audit
- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Pharmaceutical Systems Design
- Installation & Commissioning
- Validation & VMP

➤ EMA APPROVED

M/S. ENDOCEUTICS

Montreal, Canada, 2018-2020

FACILITY: VAGINAL OVULES, OEL3
(EPCMV)

- cGMP Compliance Audit
- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Pharmaceutical Systems Design
- Installation & Commissioning
- Validation & VMP

➤ FDA & EMA APPROVED

M/S. IPSEN BEAUFOUR

Dreux, France, 2005-2008

FACILITY: ONCO OSD OEL5

- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Pharmaceutical Systems Design

➤ FDA & EMA APPROVED

M/S. PHARMAGHREB

Tunis, Tunisia, 2015-2016

FACILITY: ONCOLOGICAL ORAL
SOLID DOSAGE OE5

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Basic Engineering BOD
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Containment Technology

➤ FDA & EMA APPROVED

We *Process*, *Build*, *Engineer*

M/S. PHARMAGHREB
Tunis, Tunisia, 2015-2016

**FACILITY: HORMONAL SOLID
DOSAGE, OEL5**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning

➤ FDA & EMA APPROVED

M/S. MEDICEF - HIKMA
Tunis, Tunisia, 2015

**FACILITY : CEPHALOSPORINE
BETA-LACTAME ORAL SOLID
DOSAGE OEL3**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Risk Analysis & Preventive
Actions
- Audit
- Training

➤ FDA APPROVED

M/S. MEDIS
Tunis, Tunisia, 2014

**FACILITY: OSD FORM
ONCOLOGICAL OEL5**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Audit & Compliance Review
- Gap & Risk Analysis &
Preventive Actions
- Layout Design Re-Engineering
- Containment Technology
- FAT

➤ FDA & EMA APPROVED

M/S. CONFIDENTIAL
Tunisia, 2013

**FACILITY: OSD FORM & BETA-
LACTAM**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning

➤ FDA & EMA APPROVED

We *Process*, *Build*, *Engineer*

M/S. MEDIS Laboratories
Nabeul, Tunisia, 2014-2015

FACILITY: INJECTABLE &
ONCOLOGICAL OEL5

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Audit & Compliance Review
- Gap & Risk Analysis & Preventive Actions
- Layout Design Re-Engineering
- Containment Technology
- FAT

➤ FDA & EMA APPROVED

M/S. IPSEN BEAUFOUR
Dreux, France, 2005-2008

FACILITY: ONCO INJECTABLE OEL4

- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Pharmaceutical Systems Design
- Installation & Commissioning
- SOP
- Validation

➤ FDA & EMA APPROVED

/S. PIERRE FABRE
Pau, France, 2007

FACILITY : STERILE OEL5

- Conceptual Design
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Pharmaceutical Systems Design
- Installation & Commissioning
- SOP
- Validation

➤ FDA & EMA APPROVED

M/S. Denis Giroux Laboratories
Montreal, Canada, 2005

FACILITY: F&F SV-USP797-HP-OEL5

- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Process Eqpmt / Engineering
- Construction Management
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Installation & Commissioning
- SOP
- Validation

➤ HEALTH CANADA APPROVED

*We **P**rocess, **B**uild, **E**ngineer*

M/S. APTALIS
Montreal, Canada, 2014-2015

**FACILITY: SUPPOSITORY
FORM OEL5**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Gap Analysis & Preventive Actions GAPA
- Risk Analysis & Preventive Actions RAPA
- Audit & Compliance Revue
- Design Review
- Containment Technology

➤ FDA & EMA APPROVED

M/S. CONFIDENTIAL
Tunisia, 2013

**FACILITY: OSD FORM & BETA-
LACTAM, OEL3**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- Containment Technology
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design

➤ FDA & EMA APPROVED



HEALTH CANADA
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BIOTECHNOLOGY & BIOSAFETY CONTAINEMENT PROJECTS REFERENCES



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INGÉNIERIE _ ETUDES TECHNIQUES _ ESSAI ET CONTRÔLE _ QUALIFICATION _ MÉTROLOGIE

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M/S. GREENCROSS
Canada, 2016-2018, BSL2

FACILITY: Blood Plasma Fractionation
Sub-Contract / BOSCH

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Basic Engineering
- Containment Equipment
- Process Eqpmt / Engineering
- Clean Utilities & Piping Design
- Validation Equipment & Clean Utilities

➤ FDA & EMA APPROVED

M/S. PURLAB
Algeria, 2018-2021

FACILITY : OEL5 CYTOTOXIC
BIOSIMILAR DESIGN FACILITY

- Conceptual Design
- Basic Engineering
- Detailed Engineering
- Process Eqpmt / Engineering
- Construction Management
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Installation & Commissioning
- SOP, Validation, PAI

➤ EMA Approved

M/S. DBI – DEMO BATCH
France, 2006-2007, CMO, BSL2

FACILITY: CMO BSL2 VACCINE
DESIGN FACILITY

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Basic Engineering
- Containment Equipment
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design

➤ FDA & EMA APPROVED

M/S. LABORIUM BIOPHARMA
Canada, 2004-2007, CMO, BSL2

FACILITY : BSL2 CMO VACCINE
DESIGN FACILITY

- Conceptual Design
- Basic Engineering
- Detailed Engineering
- Process Eqpmt / Engineering
- Construction Management
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Installation & Commissioning
- SOP, Validation

➤ HEALTH CANADA, EMA, FDA
APPROVED

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M/S. BIOVEX
Canada, 2005, , CMO, BSL2

**FACILITY: BSL2 CMO VACCINE
DESIGN FACILITY**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies

➤ FDA & EMA APPROVED

**M/S. LABORATOIRES DENIS
GIROUX (GALENOVA INC.)**
St-Hyacinthe, Canada, 2011

**FACILITY: CMO, BSL2, ASEPTIC
FILL & FINISH LABS (USP797)**

- Conceptual Design
- Basic Engineering
- Detailed Engineering
- Process Eqpmt / Engineering
- Construction Management
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Installation & Commissioning
- SOP
- Validation
- HEALTH CANADA APPROVED

M/S. MCGILL UNIVERSITY
Montreal, Canada, 2005

**FACILITY: BSL2 PANCREATIC CELL
LABS**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Containment Equipment
- Detailed Engineering

M/S. OM PHARMA
Switzerland, 2001-2004

**FACILITY : BSL2 VACCINE
TURNKEY FACILITY DESIGN**

- Conceptual Design
- Basic Engineering
- Detailed Engineering
- Process Eqpmt / Engineering
- Construction Management
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Installation & Commissioning
- SOP
- Validation
- EMA, FDA APPROVED



BIOTECHNOLOGY & BIOSAFETY CONTAINEMENT PROJECTS REFERENCES



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M/S. STERIS
Montreal, Canada, 2003

FACILITY: BSL2 LABORATORY
(Washer & Decontamination Machines
for Hospitals)

- Conceptual Design
- Basic Engineering
- Detailed Engineering
- Process Eqpmt / Engineering
- Construction Management
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Installation & Commissioning
- SOP
- Validation
- HEALTH CANADA APPROVED

M/S. HÔPITAL MAISONNEUVE-ROSEMONT
Montreal, Canada, 2003

**FACILITY: BSL3 DESIGN FOR
LABS/HOSPITAL**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Basic Engineering
- Containment Equipment
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design



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ONCOLOGICAL & OSD - CONTAINMENT PROJECTS REFERENCES

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We save lives and the planet

M/S. PURLAB

Oran, Algeria, 2018-2021
(EPCMV)

FACILITY: OSD Oncological, OEL5

- cGMP Compliance Audit
- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Pharmaceutical Systems Design
- Installation & Commissioning
- Validation & VMP

➤ EMA APPROVED

M/S. ENDOCEUTICS

Montreal, Canada, 2016-2017

FACILITY : VAGINAL OVULES, OEL3

- cGMP Compliance Audit
- Conceptual Design
- Basic Engineering
- Detailed Engineering URS/FDS
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Containment Equipment
- Clean Utilities & Piping Design
- Pharmaceutical Systems Design
- Installation & Commissioning
- Validation & VMP

➤ FDA, EMA, HC APPROVED

M/S. PHARMAGHREB

Tunis, Tunisia, 2015-2016

FACILITY: ORAL SOLID DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Pharmaceutical systems

M/S. PHARMAGHREB

Tunis, Tunisia, 2015-2016

FACILITY: HORMONAL SOLID
DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Containment Equipment

➤ US-FDA & EMA

We *Process*, *Build*, *Engineer*

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M/S. PHARMAGHREB
Tunis, Tunisia, 2015-2016

FACILITY: ONCOLOGICAL ORAL
SOLID DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Containment Technology

US-FDA & EMA

M/S. MEDICEF - HIKMA
Tunis, Tunisia, 2015

FACILITY : CEPHALOSPORINE
BETA-LACTAME ORAL SOLID
DOSAGE OEL3

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Risk Analysis & Preventive
Actions
- Audit
- Training

M/S. MEDIS
Tunis, Tunisia, 2014

FACILITY: OSD FORM
ONCOLOGICAL OEL5

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Audit & Compliance Review
- Gap & Risk Analysis &
Preventive Actions
- Layout Design Re-Engineering
- Containment Technology
- FAT

➤ US-FDA & EMA

M/S. CONFIDENTIAL
Tunisia, 2013

FACILITY: DRY FORM & BETA-
LACTAM

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning

➤ US-FDA & EMA

We *Process*, *Build*, *Engineer*

We save lives and the planet

M/S. PHARMAGHREB
Tunis, Tunisia, 2015-2016

FACILITY: HORMONAL SOLID
DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning
- US-FDA & EMA

M/S. MEDICEF - HIKMA
Tunis, Tunisia, 2015

FACILITY : CEPHALOSPORINE
BETA-LACTAME ORAL SOLID
DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Risk Analysis & Preventive
Actions
- Audit
- Training

M/S. SOTHEMA
Casablanca, Morocco, 2014

FACILITY: CEPHALOSPORIN

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Risk Analysis & Preventive
Actions
- Training

➤ EMA

M/S. ENDOCEUTICS
Montreal, Canada, 2015

FACILITY: SUPPOSITORY FORM

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Gap Analysis & Preventive
Actions
- Process skids
- Design Review

➤ US-FDA & EMA

We *Process*, *Build*, *Engineer*

We save lives and the planet

M/S. APTALIS
Montreal, Canada, 2014-2015

**FACILITY: SUPPOSITORY FORM
OEL5**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Gap Analysis & Preventive Actions
- Audit & Compliance Revue
- Design Review
- Engineering, Procurement & Construction Management Qualification
- Health Canada Approved
- US-FDA & EMA

M/S. PHARMADERM
Tunis, Tunisia, 2014

**FACILITY : LIQUID & SUPPOSITORY
FORM**

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Gap Analysis & Preventive Actions
- Audit & Compliance Revue
- Design Review
- Engineering, Procurement & Construction Management Qualification
- US-FDA & EMA

M/S. PRODOC
Montreal, Canada, 2014

FACILITY: ORAL SOLID DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Gap Analysis & Preventive Actions
- Audit & Compliance Revue
- Design Review
- Engineering, Procurement & Construction Management Qualification
- US-FDA & EMA

M/S. ZENITH PHARMA
Morocco, 2013-2014

FACILITY: SUPPOSITORY FORM

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Gap Analysis & Preventive Actions
- Audit & Compliance Revue
- Design Review
- Engineering, Procurement & Construction Management Qualification
- US-FDA & EMA

We *Process*, *Build*, *Engineer*

We save lives and the planet

M/S. CONFIDENTIAL
Tunisia, 2013

FACILITY: SUPPOSITORY FORM

- cGMP Compliance Audit
- Design Review
- Feasibility Studies

➤ US-FDA & EMA

M/S. GALENICA
Morocco, 2013

FACILITY : ORAL SOLID DOSAGE &
SUPPOSITORY FORM

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Gap Analysis & Preventive Actions
- Audit & Compliance Revue
- Design Review
- Engineering, Procurement & Construction Management Qualification

➤ US-FDA & EMA

M/S. PIERRE FABRE
France, 2007

FACILITY: LIQUID FORM

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning

➤ US-FDA & EMA

M/S. CEPHALON
France, 2007

FACILITY: LIQUID FORM

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Design Qualification

➤ US-FDA & EMA

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M/S. MERIAL
France, 2005

FACILITY: LIQUID FORM

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning
- Detailed Engineering

- US-FDA & EMA

M/S. AXCAN PHARMA (MCP)
CANADA (GERMANY), 2004-2005

FACILITY : ORAL SOLID DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies

- US-FDA & EMA

M/S. BECTON DICKINSON
France, 2007-2008

FACILITY: ORAL SOLID DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning

- US-FDA & EMA

M/S. IPSEN BEAUFOUR
France, 2005-2007

FACILITY: ORAL SOLID DOSAGE
OEL5

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning
- Detailed Engineering

- US-FDA & EMA

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M/S. DUCHESNAY
Montreal, Canada, 2003-2004

FACILITY: ORAL SOLID DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning
- Detailed Engineering

➤ US-FDA & EMA

M/S. FERRING
SWITZERLAND, 2003-2004

FACILITY : ORAL SOLID DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Commissioning
- Detailed Engineering

➤ US-FDA & EMA

M/S. LABOPHARM
Montreal, Canada, 2003

FACILITY: ORAL SOLID DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Racine Causes Analysis
- Onsite troubleshooting
- CAPA
- Basic Engineering
- Process Eqpmt / Engineering
- Modular Cleanroom Design
- HVAC & Layout Design
- Clean Utilities & Piping Design
- Detailed Engineering
- Commissioning
- Installation
- Site Supervision
- Validation Support
- Health Canada Approved

➤ US-FDA & EMA

M/S. PANGEO
Montreal, Canada, 2003

FACILITY: ORAL SOLID DOSAGE

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Audit & Compliance Revue
- Health Canada Approved

➤ US-FDA & EMA

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M/S. PROPHARMAL
Algeria, 2005

FACILITY: QUALIFICATION OF ORAL
SOLID DOSAGE EQUIPMENT

- cGMP Compliance Audit
- Design Review
- Feasibility Studies
- Validation Support
- Installation & Operation Qualification

➤ EMA



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ONCOLOGICAL PROJECTS REFERENCES



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4- AUDIT, GMP COMPLIANCE & PROJECT MANAGEMENT

Project	Client	Country	Date	Mandate	Details	Logo	Site
OSD Forms & Liquids	SETIF MEDIC	Algeria	2018	GMP Compliance Review & Design, AMO	cGMP, ASME-BPE, ISO-14644		www.sarlsetifmedic.dz
Clean Utilities, CIP, Sterile Injectable Units and OSD Forms	FRATER-RAZES	Algeria	2018	AMO, AU, GAPA, TT	Layouts, Clean Utilities, CIP, Sterile Injectable Units and OSD Forms		www.frater-razes.com/
Clean Utilities, CIP, Sterile Injectable Units and OSD Forms	UNIMED	Tunisia	2018	AU, RAPA GAPA	Clean Utilities, CIP, Sterile Injectable Units and Dry Forms		www.unimed.co.m.tn
PKG equipment manufacturing & Automation	AMD	Canada	2018	Training	GMP & HACCP, ISO-22000		http://www.amdinc.ca/
Many Forms	Gasco, Goodhue, St-Germain McKesson	Canada	2013	AU, GAPA EXPERT	Cold Room Warehouse		
EXPLOSION Risks Audit & Regulatory conformity review	Church & Dwight	Canada	2011	FS AU GAPA RAPA	Solvent (Ethanol) flammable & Explosive NFPA 30, NPI_2005 NFC 2010		www.churchdwight.ca/
	Parima Groupe	Canada	2011				www.groupeparima.com/
OTC & Health Natural Products	Johnson & Johnson	Canada	2011	FS AU	cGMP		www.incanada.com
Compounding Skids	Galderma	Canada	2011	FS BOD	cCMP ASME-BPE		www.galderma.com/
Pharmaceutical warehouse	Pfizer SANDOZ	Canada	2011-2012	DE	cGMP		www.pfizer.ca
Conception Installation R&D	CRIP Biorefinery	Canada	2009-2011	BOD GP	cGMP		www.biorefinery.ws

5- CLEAN UTILITIES & PHARMACEUTICAL SYSTEMS

Project	Client	Country	Date	Mandat	Detail	Logo	Site
OSD Forms & Liquids	SETIF MEDIC	Algeria	2018	GMP Compliance Review & Design, AMO	cGMP, ASME-BPE, ISO-14644		www.sarlsetifmedic.dz
Clean Utilities, CIP	FRATER-RAZES	Algeria	2018	AMO, AU, GAPA, TT	Layouts, Clean Utilities, CIP, Sterile Injectable Units and OSD Forms		www.frater-razes.com/
Clean Utilities, CIP	UNIMED	Tunisia	2018	AU, RAPA GAPA	Clean Utilities, CIP, Sterile Injectable Units and Dry Forms		www.unimed.com.tn
Purified Water CIP, HVAC COMP AIR	ENDOCEUTICS	Canada	2016 - 2018	BOD, DE, Validation	cGMP, ASME-BPE		www.endoceutics.com
CIP	BOSCH GREEN CROSS	Canada	2016 - 2017	PM, TM FAT, SAT, IQ, OQ	cGMP, ASME-BPE		www.bosch.ca www.greencrossbt.com
Purified Water CIP, HVAC, Process Compressed Air	Pharmaghreb	Tunisia	2015 - 2016	BOD	cGMP ASME BPE ISO-14644 ISO-8573		www.pharmaghreb.com/
Purified water, CIP, HVAC, Process Compressed Air	CONFIDENTIAL	Tunisia	2013	FS BOD	CGMP ASME BPE ISO-14644 ISO-8573 Safe Brige, HP3	Confidentiel	Confidentiel
Purified water, CIP, HVAC, Process Compressed Air	PHARMADERM Topical solutions & creams :	Tunisia	2014	GAPA, AU/DR EPCMV	CGMP ASME BPE ISO-14644 ISO-8573		www.pharmaderm.com
HVAC, Purified water, Process Compressed Air	COOPER Pharma	Tunisia	2014	AU, GAPA, DR	CGMP ASME BPE ISO-14644 ISO-8573		http://cooperpharma.ma/

Purified water	CPCM Pharma	Algeria	2014	AU, GAPA, DR	CGMP ASME BPE	LABORATOIRE CPCM PHARMA	
HVAC	Aptalis	Canada	2014	GAPA	CGMP ASME BPE ISO-14644		www.aptalispharma.com
HVAC	Prodoc	Canada	2014 2005	GAPA, AU, PM	CGMP ISO-14644		www.prodoc.qc.ca
Purified water HVAC	ZENITH Pharma	Morocco	2014	GAPA, AU, PM	CGMP ASME BPE ISO-14644		www.zenithpharma.ma
Purified water	Pharmascience	Canada	2011	FS, PE BOD, ID	CGMP ASME BPE		www.pharmascience.com/

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FS Feasibility study

BOD Basis of design

DE Detailed engineering

P Purchasing

I

Installation

C

Commissioning

PM

Project management

AU

Audit & Conformity review

S

Site Supervision

V

Validation support

PE

Process engineering

Biorefining & Industrial Bioprocesses	École Polytechnique de Montréal	Canada	2011-2012	Lectures	cGMP	 ÉCOLE POLYTECHNIQUE MONTREAL	www.polymtl.ca/
	INRS	Canada	2011-2012	Lectures	cGMP	 INRS Université d'avant-garde	www.inrs.ca/
Refining industries of beets and cane sugar	Cosumar, ONA Group	Morocco	1991-2000	BOD GP	BPI HACCP GFSI	 كوسومار COSUMAR	www.cosumar.co.ma
Marine oil refining, Shortning and Chocolate Manufacturing Plants	Baltimar, Richbond Group	Morocco	2000	BOD Process Automation GP	BPI HACCP GFSI	 بالتيمار BALTIMAR	www.baltimar.ma

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FS Feasibility study

BOD Basis of design

DE Detailed engineering

P Purchasing

I Installation

C Commissioning

PM Project management

AU Audit & Conformity review

S Site Supervision

V Validation support

PE Process engineering

6 – Pharmaceutical Warehouses

Project Type	Customer	Country	Date	Mandate	Specific Design	Logo	WebSite
Vaginal Ovules	Endoceutics	Canada	2016-2018	Process & Clean Utilities Skids, URS, DE, Validation	cGMP, ASME-BPE, ISO-14644, HP3		www.endoceutics.com
OSD forms, Creams	Cooper Tunisie	Tunisia	2015-2016	AU, TRG, DR, PAI	cGMP ASME-BPE		
Oral Solid Dosage	Pharmaghreb	Tunisia	2015-2016	BOD	cGMP, ASME-BPE, ISO-14644		www.pharmaghreb.com/
Oncological & hormones	Pharmaghreb	Tunisia	2015-2016	BOD	cGMP, ASME-BPE, ISO-14644, Safe Bridge, HP5+		www.pharmaghreb.com/
Cephalosporine, Beta-lactame, Oral Solid Dosage	MEDICEF, HIKMA	Tunisia	2015	RAPA, AUDIT, TRG	cGMP, ASME-BPE, ISO-14644, Safe Bridge, HP3		www.hikma.com
Liquid & suppository form	PHARMADERM	Tunisia	2014	GAPA, AU/DR EPCMQ	cGMP, ASME-BPE		www.pharmaderm.com
Injectables & Oral Solid Dosage	CONFIDENTIEL	Tunisia	2013	FS, BOD	BOD for F&F & OSD	Confidential	Confidential
Dry form & Beta-lactam	Confidential	Tunisia	2013	FS, BOD	cGMP, ASME-BPE, ISO-14644, Safe Bridge, HP3	Confidential	Confidential
Oral Solid Dosage & suppository form	ZENITH Pharma	Morocco	2013-2014	GAPA, AU/DR EPCMQ	cGMP, ASME-BPE, OSD		www.zenithpharma.ma
Suppository form	Gasco, McKesson	Canada	2013-2014	AU, GAPA EXPERT	Cold Rooms & Warehouse		
BSL2 CMO Vaccine Facility Design	Laborium (CMO)	Canada	2004-2007	FS PE BOD PM	BSL2 Design & Aseptic Design cGMP, ASME-BPE		www.laboriumbio.com/
Oral Solid Dosage	Duchesnay	Canada	2003-2004	PE BOD DE	cGMP, ASME, BPE		www.duchesnay.com

6 – Pharmaceutical Warehouses

Warehouse Design	Pfizer	Canada	2011-2012	DE	cGMP		www.pfizer.ca
Warehouse Design	SANDOZ	Canada	2011-2012	DE	cGMP		www.sandoz.ca
Warehouse Design Review	Mayne Pharma	Canada	2003-2004	BOD & PM	cGMP		www.maynepharma.com/

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FS	Feasibility Study	I	Installation	S	Site Supervision
BOD	Basis Of Design	C	Commissioning	V	Validation Support
DE	Detailed Engineering	PM	Project Management	PE	Process Engineering
P	Procurement	AU	Audit & Compliance Revue	GAPA	Gap & Risk Analysis &
EPCMQ	Engineering, Procurement, Construction Management Qualification	DR	Design Review	RAPA	Preventive Actions
		PAI	Pre-approval inspection	TRG	Training
IQ	Installation Qualification	OQ	Operation Qualification	GEP	Good Engineering Practice
HACCP	Hazard Analysis Critical Control Point				



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Thanks !



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