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Training & Consultancy

شركة فارما ارينا للتدريب و الاستشارات ش.ذ.م.م - القاهرة - بطاقة ضريبية رقم 540-639-699

SUMMER 2023

FRESH GRADS & SENIOR STUDENTS

PHARMA INDUSTRY

CAREER KICK-OFF

DIPLOMA

Know yourself
Explore options
Find your passion
Improve your resume
Improve chances to secure a job

- Online live video training
- 10 Modules
- 10 Training day's
- 60 Training hours
- Certificate of completion

MODULE 1
Pharmaceutical industry overview & regulatory framework

MODULE 2
Personnel

MODULE 3
Pharmaceutical plant

MODULE 4
Production operations & control

MODULE 5
Quality Assurance

MODULE 6
Qualification & Validation

MODULE 7
Quality control

MODULE 8
Research & Development

MODULE 9
Pharmaceutical engineering

MODULE 10
Supply chain

training@pharmaarena.com
+2 010 180 1 3383

KNOW. YOUR. WORTH.

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Training Scope & Schedule:

10 Modules – 10 training days – 60 training hours

Module 1: Pharma industry overview
Module 2: Personnel
Module 3: Pharmaceutical plant
Module 4: Production operations
Module 5: Quality assurance
Module 6: Qualification & validation
Module 7: Quality control
Module 8: Research & Development
Module 9: Pharmaceutical Engineering
Module 10: Supply chain

	Day	Date		Time	Module	
Day 1	Saturday	8th	July	10:00am – 12:30pm 1:00pm – 4:00pm	Module 1	Pharma industry overview
Day 2	Saturday	15th			Module 2	Personnel
Day 3	Saturday	22nd			Module 3	Pharmaceutical plant
Day 4	Saturday	29th			Module 4	Production operations
Day 5	Saturday	5th	August		Module 5	Quality assurance
Day 6	Saturday	12th			Module 6	Qualification & validation
Day 7	Saturday	19th			Module 7	Quality control
Day 8	Saturday	26th			Module 8	Research & Development
Day 9	Saturday	2nd	Sept.		Module 9	Pharmaceutical Engineering
Day 10	Saturday	9th			Module 10	Supply chain

Training fee:

Egyptians:

Basic fee: 5000 EGP

Early bird registration & payment till 21st June: 4000 EGP

Non-Egyptians:

Basic fee: 350$

Early bird registration & payment till 21st June: 300$

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شركة فارما ارينا تصدر فواتير ضريبية الكترونية فور طلبها

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Payment methods:

يُرجى قراءة هذا الكتيب بتمعّن وفهمه والتأكد ان البرنامج يناسب متطلباتك قبل اتمام الدفع

Bank transfer
Ahli national bank البنك الاهلى المصري
Pharma arena فارما ارينا ش.ذ.م.م
Acc. No.: **04830710349566010 11**

Vodafone cash
+2 010 180 1 3383

Registration & Booking:

For support: Call us or send a WhatsApp message to **+2 010 180 1 3383**

After payment, **Send an email**: بعد اتمام الدفع الرجا ارسال بريد الكتروني

To: **training@pharmaarena.com**

Email subject: **Pharma arena – Pharma industry diploma + Your full name**

Email body: Please include:

- *Your full name* الاسم بالكامل كما تريد ان يظهر بشهادة الحضور
- *Phone number (WhatsApp)* رقم المحمول (الواتساب) حتي نتمكن من التواصل معك
- *University / Faculty & Graduation year or current class* الجامعه / الكلية / السنه الدراسيه

Attachment: **Please attached scanned proof of payment**
الرجا ارفاق صورة من ايصال الدفع / التحويل البنكى

After registrationyou will receive a phone call & an email **to confirm your registration & review your data.**

You will be automatically added to the **training Whatsapp group** where you will receive notifications.

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Training invitation link & Credentials

Three days before training You will receive An email + Whats app message containing the **online invitation link & Credentials**

For more information / Help

Call us or send a WhatsApp message to **+2 010 180 1 3383**

Course description:

The pharmaceutical industry kick-off diploma is a comprehensive introduction to the pharmaceutical industry and GMP compliance throughout the pharmaceutical product life cycle.

The pharmaceutical industry kick-off diploma is a tailored program aiming at preparing and qualifying a new generation of graduates / senior students within an advanced professional framework capable of meeting the needs of the labor market locally, regionally, and internationally

Certification

Certificates will be issued upon successful completion of the program from:

تصدر الشهادات بعد استكمال البرنامج من:

- **Pharma arena, Training & consultancy L.L.C - Cairo / Egypt**

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This diploma is not a degree award and hours of training do not count toward credit hours in other academic programs.

لا يهدف هذا الدبلوم إلى الحصول على درجة أكاديمية ولن يتم اعتماد الساعات التدريبية كساعات معتمدة للبرامج الأكاديمية الأخرى.

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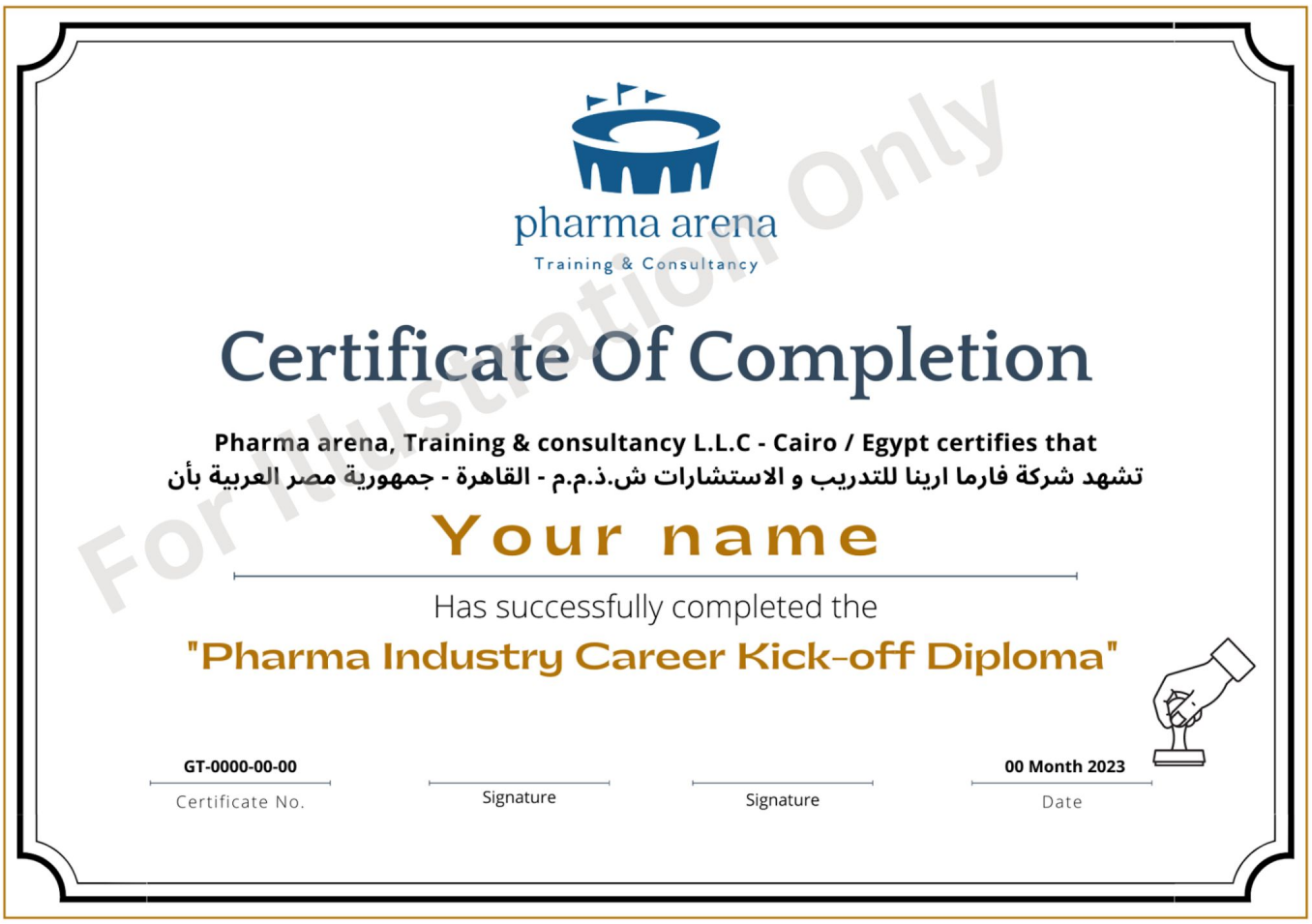
Certificate Of Completion

You will receive the **signed & stamped certificate of completion** within **10 working days** after completion of the program



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Training highlights:

MODULE 1
Pharmaceutical industry overview & regulatory framework

1-1 Peculiarities of the pharmaceutical industry
1-2 The pharmaceutical industry, one of the most regulated industries

1-3 GMP Regulatory bodies

- FDA
- Eu / EMEA
- WHO
- PICS
- ICH
- MHRA
- TGA
- USP
- BP
- EP

1-3 Typical product manufacturing life cycle
1-4 Typical technical operations human structure

- Quality
  - Quality assurance
    * Document control
    * QMS
    * Qualification & validation
    * IPQA – IPQC – IPC
    * Reviewer
    * Audit & compliance
  - Quality control
    * RM
    * PM
    * IP & FP
    * Stability
    * GLP
    * Investigation
    * Microbiology
- Supply chain
  - Planning
  - Purchasing
  - warehousing
- Engineering
  - Utilities
  - Maintenance
- Production
- Research & development
  - Formulation
  - Methodology
- Regulatory Affairs
- Pharmacovigilance

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Training highlights:

MODULE 2
PERSONNEL

2-1 Job descriptions
2-2 Training
2-3 Personnel Qualification
2-4 Gowning
2-5 Hygiene & Health
2-6 Qualified person **QP**

MODULE 3
Pharmaceutical plant

3-1 Design criteria
3-2 Flow
3-3 Cleanroom concept
3-4 **HVAC** (Heat, ventilation & air conditioning)
3-5 Pharmaceutical plant layout

MODULE 4
Production operations & control

4-1 Premises & equipments
4-2 Manufacturing
4-3 Packaging
4-4 Raw & Packaging materials
4-5 Process flow charts
4-6 Cleaning, sanitation & hygiene
4-7 Environmental control & monitoring
4-8 Cross-contamination & mixups
4-9 Contract Manufacturing
4-10 Dosage forms
    4-10-1 Oral solids
    4-10-2 Oral liquids
    4-10-3 Semisolids
    4-10-4 Sterile forms
    4-10-5 Other dosage forms

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Training highlights:

MODULE 5
Quality Assurance

5-1 Quality cascade
5-2 Quality management system **QMS**
5-3 Site master file **SMF**
5-4 Documentation and document control
5-5 Quality management review **QMR**
5-6 Quality risk management **QRM**
5-7 Change control
5-8 Complaints
5-9 Product Recall
5-10 Deviation handling
5-11 Internal audits
5-12 Corrective /Preventive actions **CAPA**
5-13 Product Quality Review **PQR**
5-14 External inspections
5-15 Training & development
5-16 Automated quality assurance instrumentation **AQAI**
5-17 Supplier management
5-18 Batch record review and batch release
5-19 Data integrity

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Training highlights:

MODULE 6
Qualification & Validation

6-1 The validation cascade / Pyramid
6-2 Validation practices
6-3 Impact assessment
6-4 Traditional validation approach
6-5 Validation, the life cycle approach
6-6 Validation master plan
6-7 Critical process parameters **CPP** & Critical quality attributes **CQA**
6-8 Design qualification **DQ**
6-9 Installation qualification **IQ**
6-10 Operational qualification **OQ**
6-11 Performance qualification **PQ**
6-12 Process validation **PV**
6-13 Cleaning validation **CV**
6-14 Analytical method validation **AMV**
6-15 Validation of **HVAC** system
6-16 Validation of pharmaceutical water system
6-17 Sterile operations validation
6-18 Thermal sterilization
6-19 Sterilization by filtration
6-17 Media fill operations

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Training highlights:

MODULE 7
Quality Control

7-1 Good laboratory practices GLP
7-2 Quality control labs design
7-3 Pharmacopeial compliance & review
7-4 Sampling & sample management
7-5 Raw material testing
7-6 Finished product testing
7-7 Packaging material testing
7-8 Stability testing
7-9 Long-term and ongoing stability studies
7-10 Out Of Specifications (**OOS**) and Out Of Trends (**OOT**) handling.
7-11 Reference and working standards
7-12 Retained samples
7-13 Microbiology testing
7-14 Testing Instruments qualifications and calibration
7-15 Weighing and balances
7-16 Pharmaceutical water testing
7-17 QC test report
7-18 **IPC** testing
7-19 Materials and products testing and release
7-20 **LIMS** & Data Integrity

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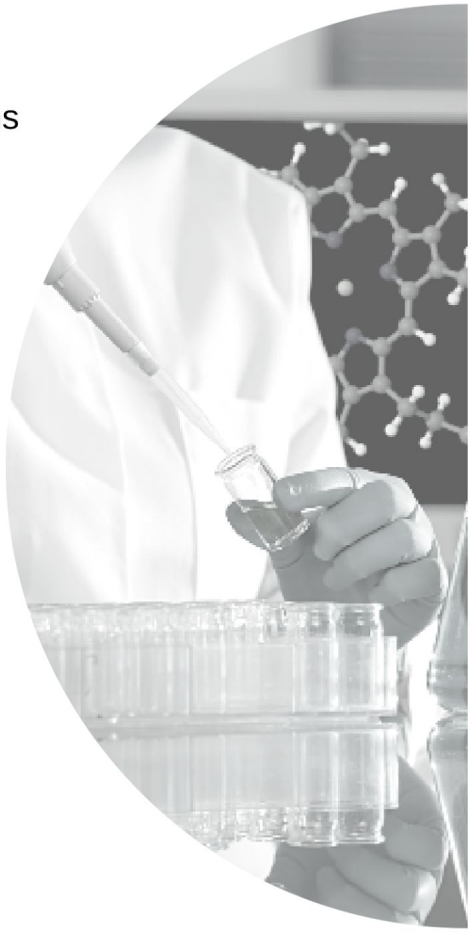
Training highlights:

MODULE 8
Research & Development

8-1 Pre-formulation studies
8-2 Raw material, Intermediate & finished product specifications
8-3 API sourcing and Supplier qualification
8-4 DMF evaluation
8-5 Formulation studies
8-6 Quality By Design (QBD)
8-7 Analytical methods development, validation, and transfer
8-8 Accelerated stability studies
8-9 Shelf life evaluation
8-10 R&D, Pilot & Engineering batches
8-11 Post-approval changes



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Training highlights:

MODULE 9
Pharmaceutical engineering

9-1 Manufacturing Facility Design
9-2 Utilities
- 9-2-1 Direct impact utilities
  - 9-2-1-1 HVAC
  - 9-2-1-2 Pharma water system
- 9-2-2 Indirect & Non-impact utilities
  - 9-2-2-1 Compressed air
  - 9-2-2-2 Other compressed gases
  - 9-2-2-3 Industrial steam
  - 9-2-2-4 Chilled water

9-5 Maintenance
- 9-5-1 Corrective maintenance
- 9-5-2 Preventive maintenance
- 8-5-3 Predictive maintenance

9-6 Equipment qualification
9-7 Building management system (BMS)
9-8 Calibration
9-9 Computer system

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Training highlights:

MODULE 10
Supply chain

10-1 Premises & facilities / Pharmaceutical warehouse design criteria
10-2 Procedures & Records
10-3 Security
10-4 Contamination
10-5 Product Integrity
10-6 Pest and rodents control
10-7 Product traceability & stock control
10-8 Temperature monitoring & control
10-9 Thermal mapping and qualification of stores
10-10 Physical separation Vs Random access
10-11 ERP systems (Enterprise resource planning)
10-12 Receiving process
10-13 Sampling facility & process
10-14 Environmental monitoring and control
10-15 Cool & cold stores
10-15 Cold chain management
10-17 Distribution vehicles
10-18 Recall & returned goods management
10-19 Reject handling
10-20 Counterfeit & falsified products

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توجيهات و ارشادات

1- بمجرد التسجيل و دفع قيمة التدريب **سيتم ضمك اوتوماتيكيا الي جروب ال WhatsApp** الخاص بالتدريب حيث ستتسلم الاشعارات ذات الصلة
As soon as registration & payment are completed, you will be automatically added to the training WhatsApp group

2- سيتم ارسال **رابط الدخول و اسم المستخدم و كلمة السر** قبل بداية التدريب بوقت كافي
You will receive training link & credentials sufficient time before training start

3- الرجا تسجيل الدخول **بنفس الاسم الذي قمت بتسجيله** عند طلب الانضمام
Please login using the same name used for registration

4- تأكد ان **الاتصال بالانترنت** يعمل و انك تتواجد في مكان به **تغطية جيدة للشبكة**
Make sure that your internet connection is working & that network coverage is adequite

5- يفضل الاتصال عن طريق **الكمبيوتر / لابتوب** و ليس عن طريق الهاتف
Please connect through a computer or laptop

6- تأكد من وجود **مصدر للشحن الكهربائي** بالقرب منك
Ensure you have a nearby source of power / Electric socket

7- حاول ان تتواجد في **مكان هادئ** لتفادي التشويش اثناء التدريب
Please avoid crowded / public places

8- يفضل استعمال **سماعة جيدة**
For a good online experience, try using a good ear speaker

9- **يسمح بالدخول** بدايه من الساعه 9:45 صباحا و حتي 10:10 صباحا **بتوقيت القاهرة**
All announced time are reference to cairo local time

10- الرجا من الجميع الاتصال **بوضع Mute** حتي يطلب تفعيل الاتصال الصوتي
Please login in mute status

11- عند تفعيل الاتصال الصوتي ،، **الرجا التزام الهدوء**
When unmuted, please stay quiet

12- تفعيل **الاتصال بالفيديو اختياري** ولكن سيطلب منك تفعيل الفيديو لاخذ لقطه تذكاريه
Using video is optional

13- **في حال فقدت الاتصال** ،، قم بالدخول مرة اخري و سيقوم الادمن بالسماح لك بالدخول مرة اخري
If disconnected, simply, reconnect & the training admin. will immediately let you in