Doc nº:	QQGMP-003
Replaces to:	QQGMP-002
Title:	**STANDARD PRE-AUDIT QUESTIONNAIRE *FARMAQEMICAL PRODUCTS***

1.	**COMPANY NAME**	***QUALITY CHEMICALS S.L.***
2.	**ADDRESS**	*C/ Fornal 35, 08292 Esparreguera (Barcelona, Spain)*
3.	**YEAR OF FOUNDATION**	*1997*
4.	**MANUFACTURING SITE**	***QUALITY CHEMICALS S.L. / PURITY CHEMICALS S.L.***
5.	**MANUFACTURING SITE ADDRESS**	***QUALITY CHEMICALS S.L.*** *C/ Fornal 35 08292 Esparreguera (Barcelona, Spain)* ***PURITY CHEMICALS S.L.*** *Av. Tren Expreso, 82-84 34200 Venta de Baños (Palencia, Spain)*
a.	Date of construction of production facility	*QUALITY CHEMICALS: 2000 / PURITY CHEMICALS: 2009*
b.	Contact person	*Lluís Aragonès*
c.	Position	*General Manager*
d.	Telephone	*+34 979 76 10 97*
e.	e-mail	*qemical@qualitychemicals.com*
6.	**COMPANY DATA**	
f.	web	*www.qualitychemicals.com* *www.purity-chemicals.com*
g.	Certifications (please attach a copy of the certificates):	
i.	Quality	*ISO 9001:2008*
ii.	Environmental	*ISO 14001*
iii.	Risk and safety	*OSHAS 18001*
iv.	Other	*GMP certificate (AEMPS)* *ISO 22000*
v.	In process of implementing:	-
7.	**HUMAN RESOURCES**	
h.	Number of employees	*75 (Quality Chemicals: 55. Purity Chemicals: 20)*
i.	Production	*43 (Quality Chemicals: 28. Purity Chemicals: 15)*
1.	Production plant	*35*
2.	Warehouse	*8*
ii.	Engineering and maintenance	*4*
iii.	Quality Unit	*12*
1.	Quality control	*9*
2.	Quality management	*3*
iv.	HSE	*1*
v.	R&D	*2*
vi.	Sales	*5*
vii.	Human resources	*1*
viii.	Rest of departments	*7*
i.	Is Quality Unit independent from production?	*Yes*
j.	Who Quality Assurance reports to?	*Technical Manager*
k.	Does a training plan for employees exist?	*Yes*
l.	Are there records of training for employees?	*Yes*
m.	How many hours are spent on training per employee / year?	*30 h*

8.	**MANAGEMENT OF MATERIALS**	
a.	Is a lot number assigned to the raw materials?	*Yes*
b.	Is a lot number assigned to the finished products?	*Yes*
c.	Is there a procedure for the releasing of materials?	*Yes*
d.	Is the releasing of materials recorded?	*Yes*
e.	Are all the materials/batches tested prior to use/shipping?	*Yes.*
f.	Is there a record of the operations of analysis?	*Yes*
g.	Are CoA of the shipped batches issued?	*Yes*
h.	How many years is documentation of production and analysis kept?	*7 years*
9.	**PRODUCTION**	
a.	Productive capacity (kg/year)	*Aprox. 1,500 Tn/year*
b.	Are production methods written and approved?	*Yes*
c.	Are production methods validated? If yes, please write the code of the Validation Master Plan (VMP)	*Yes*
d.	Is the production documented in manufacturing sheets with information of raw materials, batches, operations, workers and supervision?	*Yes*
e.	Is there a preventive maintenance plan for equipments?	*Yes*
f.	Is there a calibration plan for equipment/measuring instruments in production plant?	*Yes*
g.	Does production equipment have an unambiguous reference that relates to the production documentation?	*Yes*
h.	Are deviations in production registered and/or investigated?	*Yes*
i.	Are critical parameters in the production process defined?	*Yes*
j.	Are there measures to prevent cross-contamination in production plant?	*Yes*
k.	Is there a plan for cleaning the production plant equipment?	*Yes*
l.	Are cleaning operations registered?	*Yes*
m.	Are products manufactured in dedicated or multipurpose equipments?	*Multipurpose equipments*
n.	In case of multipurpose plant, are products manufactured in the same equipment/facilities which manufacture pesticides, herbicides, penicillinic derivatives, hormones, cephalosporines, sensitizing and anti-cancer products?	*No*
o.	Please describe the quality of water used in production	*Deionized Water*
p.	Please describe the quality of the air in the last production step	*ISO 8 Class D*

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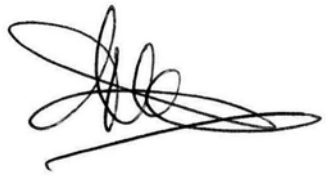
10. QUALITY		
a.	Does the company have a Quality Manual?	*Yes*
b.	Who performs the sampling of finished products?	*Qualified operators*
c.	Is there a formally approved quality specification for the product? If yes, does a change control procedure exist?	*Yes*
d.	Are all the batches analyzed and formally approved or refused?	*Yes*
e.	¿Does Quality Chemicals / Purity Chemicals retain a sample of every batch? How long?	*Yes. 7 years*
f.	Is there a calibration procedure for analytical equipment?	*Yes*
g.	Does Quality Chemicals / Purity Chemicals carry out stability studies?	*Yes*
h.	What's the expiry date / retest date of the product?	*Determined by stability test according to ICH Q1A (R2)*
i.	Are products affected by BEE/TSE, GMO, dioxins? Can you issue a certificate?	*No. We can issue a certificate.*
j.	Does Quality Chemicals / Purity Chemicals perform a qualification of suppliers?	*Yes*
k.	Does Quality Chemicals / Purity Chemicals have a procedure for management of non conformities?	*Yes*
l.	Does Quality Chemicals / Purity Chemicals have a change control procedure?	*Yes*
m.	Does Quality Chemicals / Purity Chemicals carry out product quality review?	*Yes*
n.	Does Quality Chemicals / Purity Chemicals have a procedure for management of customer complaints?	*Yes*
o.	Does Quality Chemicals / Purity Chemicals carry out internal audits?	*Yes*
p.	Is there a CAPA program in place?	*Yes*
q.	Would Quality Chemicals / Purity Chemicals allow to:	
	i. Visit tour facilities	*Yes*
	ii. Perform a quality audit of production and quality control processes	*Yes*
r.	In case of a change in the process o specifications affecting the quality of the product, would Quality Chemicals / Purity Chemicals inform their customers?	*Yes*
s.	Do Quality Chemicals / Purity Chemicals have customer quality audits? How many and how often?	*Yes. About 10-15 audits per year*

11. ENVIRONMENT AND SAFETY		
a.	Is there a system in place in order to prevent job risks?	*Yes*
b.	Are accidents at work recorded and investigated? Is there a CAPA system for accidents at work?	*Yes*
c.	Does the staff in Quality Chemicals / Purity Chemicals have appropriate security measures to the operations carried out?	*Yes*
d.	Does Quality Chemicals / Purity Chemicals perform environmental analysis concerning risk and safety at work?	*Yes*
e.	Does Quality Chemicals / Purity Chemicals have an internal emergency plan?	*Yes*
f.	Does Quality Chemicals / Purity Chemicals have a fire fighting system?	*Yes*
g.	Is there an environmental management system?	*Yes*
h.	Does Quality Chemicals / Purity Chemicals aim to reduce its potential environmental impact?	*Yes*
i.	Is Quality Chemicals / Purity Chemicals aware of REACH regulation?	*Yes*

QUESTIONNAIRE COMPLETED BY:

Name: **David Carreras**
Position: **Quality Assurance**
Date and signature:



02/06/2017