

Curriculum Vitae

Aidan Madden

September 2011

Tel: +353 87 650 4769
Email: aidan@fivepharma.com
www.fivepharma.com



Current Role

- Since 2003, Managing Director and Senior Consultant with **FivePharma**, a company offering tailored services to the pharmaceutical and allied sectors.
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Education Summary

- 2004, **IRCA Lead Auditor Training Programme**, Ireland
- 2000, **Diploma in Pharmaceutical Manufacturing Technology**, Trinity College Dublin. This Diploma fulfills the academic requirements of the **Qualified Person** as defined by the EU Directive
- 1996, **MSc** in Immunochemistry, National University of Ireland, Galway, Ireland.
- 1987, **Higher Diploma in Education**, National University of Ireland, Galway, Ireland
- 1986, **BSc** in Biochemistry and Microbiology, National University of Ireland, Galway, Ireland

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Work Experience Summary

2003 to Present

- Managing Directive and Senior Consultant with FivePharma. In this role Aidan has performed the following duties:
 - Acting as a **Qualified Person** in a number of pharmaceutical manufacturing companies in Ireland including two companies producing sterile parenteral injections (one manufacturing in Ireland, one manufacturing in Germany). Responsible for sterility assurance requirements.
 - **Performing Audits** as Lead Auditor and a member of an Audit Team against the following reference documents):
 - ICHQ7A
 - ISO9001:2008
 - ISO13485,
 - EU GMP Volume 4 Parts 1 and 2,
 - OECD GLP,
 - Investigational Medicinal Products Legislation
 - Providing **consulting services** in GMP and ISO9001:2008
 - Providing **Training** on various topics such as:
 - Principal Tutor on the Lead Auditor Training programme (5 days, IRCA Accredited)
 - Tutor on Internal Auditor Training programme (2 days, IRCA Accredited)
 - Tutor on ISO9001:2008 Training (1 day, custom training programme)
 - Tutor on EU GMP Volume 4 custom training programmes
 - Tutor on ISO13485 custom training programmes

2001-2003

- Held the position of Quality Manager in a major manufacturer and packer of solid dose medicinal products for human use (Wyeth Medica, Newbridge, Kildare, Ireland)

1999-2001

- Held the position of Senior Microbiologist in a major producer of sterile parenteral medicinal products for human use (Baxter Healthcare SA, Castlebar, Mayo, Ireland).
 - Responsible for developing best practices bioburden controlled liquid filling operations
 - Responsible for site wide sterility assurance training programmes
 - Responsible for all sterility testing using Grade A laminar Flow Cabinet in Grade B background

1991-1999

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- Held the position of QC Manager in a company producing sterile veterinary vaccines using cell culture technology (Fort Dodge laboratories, Sligo, Ireland).
 - Responsible for all sterility testing using Grade A laminar Flow Cabinet in Grade B background
 - Responsible for managing team developing aseptic practices in Production Filling activities

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1989-1991

- Worked in a Government research laboratory investigating animal diseases (Teagasc, Fermoy, Cork, Ireland).

1986-1989

- Worked in University R&D (NUI Galway, Ireland)

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Appendix 1

Table of Audits performed by Aidan Madden and FivePharma

Date	Address	Scope	# Days	Lead Auditor or Solo	Count
Jun-96	Ireland	Corporate Standards	1	Solo	1
May-01	Ireland	Corporate Standards	1	Solo	1
Aug-02	Germany	Corporate Standards	2	Solo	1
			4	Sum	4
Jun-03	Spain	EU GMP Volume 4 Part 1	1	Solo	1
Nov-03	Italy	EU GMP Volume 4 Part 2	1	Solo	1
Nov-03	Portugal	EU GMP Volume 4 Part 1	1	Solo	1
Apr-04	Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Apr-04	The Netherlands	EU GMP Volume 4 Part 1	1	Solo	1
Apr-04	Ireland	EU GMP Volume 4 Part 1	2	Solo	1
Jun-04	Ireland	ISO17025	1	Solo	1
Jun-04	Ireland	ISO17025	1	Solo	1
Oct-04	Ireland	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Nov-04	Netherlands	EU GMP Volume 4 Part 1	1	Solo	1
			11	Sum	10
Jan-05	Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Mar-05	Turkey	EU GMP Volume 4 Part 1	2	Solo	1
Mar-05	Belgium	EU GMP Volume 4 Part 2	5	Solo	1
May-05	Turkey	EU GMP Volume 4 Part 1	1	Solo	1
Jun-05	Ireland	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Nov-05	USA	EU GMP Volume 4 Part 1	1	Solo	1
Nov-05	Ireland	ISO17025	1	Solo	1
Jun-05	Ireland	EU GMP Volume 4 Part 1	1	Lead Auditor	1
			13	Sum	8

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Jan-06	Italy	EU GMP Volume 4 Part 2	1	Lead Auditor	1
Feb-06	Brazil	EU GMP Volume 4 Part 2	1	Lead Auditor	1
Feb-06	Brazil	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Feb-06	Brazil	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Feb-06	Brazil	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Feb-06	Brazil	EU GMP Volume 4 Part 1 Part 2	1	Lead Auditor	1
Mar-06	Netherlands	EU GMP Volume 4 Part 1	1	Solo	1
Mar-06	Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Apr-06	Bulgaria	EU GMP Volume 4 Part 2	1	Solo	1
May-06	Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Jun-06	Ireland	PS9000	1	Solo	1
Jun-06	Germany	EU GMP Volume 4 Part 2	2	Solo	1
Jun-06	USA	EU GMP Volume 4 Part 1	1	Solo	1
Jul-06	Germany	EU GMP Volume 4 Part 1 Part 2	1	Solo	1
Jul-06	USA	EU GMP Volume 4 Part 1	1	Solo	1
Jul-06	USA	EU GMP Volume 4 Part 1	1	Solo	1
Jul-06	Ireland	PS9000	1	Solo	1
Oct-06	Germany	EU GMP Volume 4 Part 2	1	Solo	1
Nov-06	Hungary	EU GMP Volume 4 Part 2	1	Lead Auditor	1
Nov-06	UK	EU GMP Volume 4 Part 2	1	Solo	1
Dec-06	Belgium	EU GMP Volume 4 Part 2	1	Solo	1
Dec-06	Italy	EU GMP Volume 4 Part 2	1	Lead Auditor	1
Dec-06	Ireland	ISO13485	2	Solo	1
			25	Sum	23
Jan-07	Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Feb-07	UK	EU GMP Volume 4 Part 1	1	Solo	1
Feb-07	UK	EU GMP Volume 4 Part 1	1	Solo	1

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Mar-07	Ireland	GDP	1	Solo	1
Apr-07	Netherlands	EU GMP Volume 4 Part 1	1	Solo	1
Apr-07	Germany	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Apr-07	Germany	EU GMP Volume 4 Part 2	1	Lead Auditor	1
May-07	Ireland	ISO 13485:2003 and CFR820	1	Solo	1
Jun-07	Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Jun-07	Ireland	EU GMP Volume 4 Part 2	1	Solo	1
Jul-07	UK	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Jul-07	UK	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Aug-07	China	EU GMP Volume 4 Part 2	1	Solo	1
Aug-07	China	EU GMP Volume 4 Part 2	1	Solo	1
Aug-07	China	EU GMP Volume 4 Part 2	1	Solo	1
Aug-07	China	EU GMP Volume 4 Part 2	1	Solo	1
Aug-07	China	EU GMP Volume 4 Part 2	1	Solo	1
Aug-07	China	EU GMP Volume 4 Part 1	1	Solo	1
Sep-07	Germany	EU GMP Volume 4 Part 1	1	Solo	1
Sep-07	Germany	EU GMP Volume 4 Part 2	1	Lead Auditor	1
Oct-07	Turkey	EU GMP Volume 4 Part 1	1	Solo	1
Dec-07	UK	EU GMP Volume 4 Part 1	1	Lead Auditor	1
			22	Sum	22
Jan 08	Canada	Canadian Health Regulations	1	Solo	1
Feb 08	Germany	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Mar 08	UK	EU GMP Volume 4 Part 2	1	Solo	1
June 08	France	EU GMP Volume 4 Part 1	2	Lead Auditor	1
July 08	Canada	EU GMP Volume 4 Part 1	1	Lead Auditor	1
July 08	Canada	EU GMP Volume 4 Part 1	1	Lead Auditor	1

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July 08	UK	EU GMP Volume 4 Part 1 Annex 13	1	Solo	1
Nov 08	UK	EU 94/C 63/03 GDP	1	Lead Auditor	1
Dec 08	China	EU GMP Volume 4 Part 1	2	Lead Auditor	1
Dec 08	China	EU GMP Volume 4 Part 1	3	Lead Auditor	1
Dec 08	UK	ISO9001:2000	1	Lead Auditor	1
Dec 08	UK	PS9000	1	Lead Auditor	1
			16	sum	12
Jan 09	Ireland	EU 94/C 63/03 GDP	1	Lead Auditor	1
Feb 09	Canada	EU GMP Volume 4 Part 1 Annex 13	1	Lead	1
Feb 09	Canada	EU GMP Volume 4 Part 2	1	Lead	1
Feb 09	Canada	EU GMP Volume 4 Part 1 Annex 13	1	Lead	1
Mar 09	USA	EU GMP Volume 4 Part 1	1	Solo	1
Mar 09	USA	EU GMP Volume 4 Part 1	3	Solo	1
April 09	Netherlands	EU GMP Volume 4 Part 1	1	Solo	1
April 09	China	EU GMP Volume 4 Part 2	2	Solo	1
April 09	China	EU GMP Volume 4 Part 2	2	Solo	1
May 09	Germany	EU GMP Volume 4 Part 1	2	Lead	1
Jun 09	UK	EU GMP Volume 4 Part 1	2	Lead	1
Jun 09	UK	EU GMP Volume 4 Part 1	2	Lead	1
Jun 09	India	EU GMP Volume 4 Part 2	2	Lead	1
Aug 09	UK	EU GMP Volume 4 Part 1	2	Solo	1
Dec 09	Germany	EU GMP Volume 4 Part 2	2	Lead Auditor	1
Dec 09	Italy	EU GMP Volume 4 Part 2	2	Solo	1
Dec 09	Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Dec 09	Ireland	EU GMP Volume 4 Part 1	1	Solo	1
			29	Sum	18
Jan 10	UK	EU 94/C 63/03 GDP	1	Lead Auditor	1
Jan 10	UK	EU GMP Volume 4 Part 2	1	Solo	1
Feb 10	UK	ISO 9001:2008	1	Solo	1

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Feb 10	Germany	ISO 9001:2008	1	Solo	1
Feb 10	Italy	EU GMP Volume 4 Part 2	2	Solo	1
April 10	China	EU GMP Volume 4 Part 2	2	Solo	1
April 10	China	EU GMP Volume 4 Part 2	2	Solo	1
May 10	Germany	EU GMP Volume 4 Part 1	3	Team	1
May 10	USA	EU GMP Volume 4 Part 1	4	Team	1
June 10	Germany	EU GMP Volume 4 Part 8	2	Solo	1
June 10	Switzerland	EU GMP Volume 4 Part 2	1	Solo	1
June 10	Germany	EU GMP Volume 4 Part 1	1	Solo	1
July 10	Germany	EU GMP Volume 4 Part 1	1	Solo	1
July 10	Hungary	EU GMP Volume 4 Part 1	2	Team	1
July 10	USA	EU GMP Volume 4 Part 1	1	Solo	1
Sept 10	UK	EU GMP Volume 4 Part 1	2	Team	2
Sept 10	UK	EU GMP Volume 4 Part 1	2	Team	2
Sept 10	Germany	ISO 13485	2	Team	2
Oct 10	USA	EU GMP Volume 4 Part 1	2	Solo	1
Oct 10	Korea	Food Safety	2	Solo	1
Nov 10	USA	EU GMP Volume 4 Part 1	1	Solo	1
Nov 10	Israel	EU GMP Volume 4 Part 2	3	Solo	1
Nov 10	Germany	EU GMP Volume 4 Part 1	1	Solo	1
Nov 10	Ireland	EU GMP Volume 4 Part 1	1	Lead Auditor	1
				sum	18
Jan 11	Finland	EU GMP Volume 4 Part 2	2	Solo	1
Jan 11	Finland	EU GMP Volume 4 Part 1	2	Solo	1
Feb 11	Switzerland	EU GMP Volume 4 Part 2	2	Solo	1
Feb 11	China	EU GMP Volume 4 Part 1	2	Solo	1
Mar 11	China	EU GMP Volume 4 Part 2	2	Solo	1

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Mar 11	Germany	Food Safety	2	Solo	1
May 11	USA	EU GMP Volume 4 Part 1	1	Solo	1
May 11	USA	EU GMP Volume 4 Part 2	2	Solo	1
May 11	Ireland	EU GMP Volume 4 Part 1	1	Solo	1
May 11	Ireland	EU GDP	1	Solo	1
Jun 11	China	EU GMP Volume 4 Part 2	2	Solo	1
Jun 11	Italy	EU GMP Volume 4 Part 2	1	Solo	1
Jul 11	USA	EU GMP Volume 4 Part 1	3	Solo	1
Jul 11	USA	EU GMP Volume 4 Part 2	2	Solo	1
		Totals	205 Days		144 Audits

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Table of Training delivered by Aidan Madden and FivePharma

#	Subject	Tutor	Date	Location	# Trained
1	GMP	Aidan Madden	Oct-04	Ireland	180
2	Auditing	Aidan Madden	May-04	Ireland	96
3	GMP	Aidan Madden	Nov-04	Ireland	85
4	Auditing	Aidan Madden	Jan-05	Ireland	40
5	Auditing	Aidan Madden	Apr-05	Ireland	12
6	GMP	Aidan Madden	May-05	Ireland	17
7	GMP	Aidan Madden	May-05	Ireland	60
8	GMP	Aidan Madden	Jun-05	Ireland	6
9	GMP	Aidan Madden	Aug-05	Ireland	17
10	Good Distribution Practices	Aidan Madden	Sep-05	Ireland	10
11	Good Distribution Practices	Aidan Madden	Sep-05	Ireland	26
12	GMP	Aidan Madden	Sep-04	Ireland	8
13	Good Distribution Practices	Aidan Madden	Nov-05	Ireland	18
14	Auditing	Aidan Madden	Nov-05	Ireland	12
				2005 sum	597
15	Good Distribution Practices	Aidan Madden	Jan-06	Ireland	14
16	Good Distribution Practices	Aidan Madden	Jan-06	Ireland	18
17	Auditing LAMP/GMP	Aidan Madden	Mar-06	UK	5
18	Good Distribution Practices	Aidan Madden	Apr-06	UK	6
19	GMP	Aidan Madden	Jun-06	Ireland	84
20	Good Distribution Practices	Aidan Madden	Jul-06	UK	10
21	Auditing LAMP/GMP	Aidan Madden	Sep-06	Poland	10
22	Auditing LAMP/GMP	Aidan Madden	Sep-06	UK	8
23	Good Distribution Practices	Aidan Madden	Sep-06	Ireland	8
24	Validation	Aidan Madden	Oct-06	Ireland	5
25	Auditing	Aidan Madden	Oct-06	UK	9
26	Auditing LAMP/GMP	Aidan Madden	Nov-06	UK	7
27	Good Distribution Practices	Aidan Madden	Nov-06	UK	8
				2006 sum	196
28	Good Distribution Practices	Aidan Madden and Associates	Jan-07	Belgium	17
29	Validation	Aidan Madden	Feb-07	Israel	25
30	Internal Auditing	Aidan Madden	Mar-07	Spain	12
31	Auditing LAMP/GMP	Aidan Madden	Mar-07	UK	8
32	Good Distribution Practices	Aidan Madden and Associates	Mar-07	UK	4
33	Internal Auditing	Aidan Madden	Apr-07	Ireland	7

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34	Good Distribution Practices	Aidan Madden and Associates	May-07	Ireland	9
35	Internal Auditing	Aidan Madden	May-07	Belgium	11
36	Good Distribution Practice	Aidan Madden and Associates	Sep-07	UK	7
37	Auditing LAMP/GMP	Aidan Madden	Nov-07	UK	12
38	Good Distribution Practice	Aidan Madden	Nov-07	Holland	4
39	GMP	Aidan Madden	Dec-07	Ireland	15
40	GMP	Aidan Madden	Dec-07	Ireland	8
				2007 Sum	192
41	Auditing LAMP/GMP	Aidan Madden	Feb 08	UK	8
42	Good Distribution Practice	Aidan Madden and Associates	Mar 08	UK	12
43	Auditing LAMP/GMP	Aidan Madden	May 08	UK	8
44	Validation	Aidan Madden	June 08	Ireland	6
45	Good Distribution Practices	Aidan Madden	June 08	Russia	10
46	Validation	Aidan Madden	July 08	Ireland	14
47	Good Distribution Practice	Aidan Madden and Associates	Sept 08	UK	12
48	GMP	Aidan Madden	Nov 09	Ireland	7
49	Quality Management Systems	Aidan Madden	Nov 09	UK	18
50	Drug Registration in EU	Aidan Madden and Associates	Nov 08	Lithuania	10
51	Drug Importation into EU	Aidan madden	Nov 08	Lithuania	11
52	Auditing LAMP/GMP	Aidan Madden	Nov 08	UK	8
				2008 sum	139
53	Auditing LAMP/GMP RSSL	Aidan Madden	Feb 09	UK	9
54	Good Distribution Practices	Aidan Madden	Mar 09	UK	12
55	Auditing LAMP/GMP	Aidan Madden	Feb 09	UK	4

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56	Good Distribution Practices	Aidan Madden	Jun 09	The Netherlands	12
57	Auditing	Aidan Madden	Jun 09	Ireland	24
58	Good Distribution Practices	Aidan Madden	Jun 09	Ireland	54
59	Good Distribution Practices	Aidan Madden	July 09	Ireland	66
60	Good Manufacturing Practices	Aidan Madden	July 09	Ireland	4
61	Good Distribution Practices	Aidan Madden	Aug 09	Ireland	17
62	Good Distribution Practices	Aidan Madden	Sept 09	Ireland	19
63	Self Inspection	Aidan Madden	Oct 09	UK	13
64	Self Inspection	Aidan Madden	Oct 09	Spain	39
65	Lead Auditor	Aidan Madden and Associates	Nov 09	UK	7
66	QMS	Aidan Madden and Associates	Nov 09	UK	14
67	Good Distribution Practices	Aidan Madden	Sept 09	UK	16
				2009 sum	310
68	Self Inspection	Aidan Madden	Jan 10	UK	7
69	Self Inspection	Aidan Madden	Feb 10	Ireland	13
70	Self Inspection	Aidan Madden	Feb 10	UK	12
71	Self Inspection	Aidan Madden	Mar 10	UK	7
72	Self Inspection	Aidan Madden	Mar 10	UK	13
73	ISO 9001:2008	Aidan madden	Mar 10	Ireland	28
74	Self Inspection	Aidan Madden	Apr 10	Lithuania	13
75	Validation	Aidan Madden	Apr 10	Lithuania	20
76	Lead Auditor	Aidan Madden	June 10	UK	7
77	GDP	Aidan Madden	June 10	UK	47
78	GDP	Aidan Madden	July 10	UK	13

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79	GDP	Aidan Madden	Sept 10	Romania	7
80	GDP	Aidan Madden and Associates	Oct 10	Italy	50
81	QMS	Aidan Madden and Associates	Nov 11	UK	18
82	Lead Auditor	Aidan Madden and Associates	Nov 11	UK	13
				2010 Sum	268
83	GDP	Aidan Madden	Jan 11	Turkey	9
84	Self Inspection	Aidan Madden	Jan 11	Ireland	12
85	Change Control	Aidan Madden and Associates	Mar 11	Austria	46
86	Validation	Aidan Madden	Mar 11	Turkey	9
87	GDP	Aidan madden	Jun 11	UK	8
88	GDP / GMP	Aidan Madden	Apr 11	Ireland	12
88	GDP	Aidan Madden	Aug 11	Ireland	7
				Total	1723