

Curriculum Vitae

Aidan Madden

September 2009

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
 - **Performing Audits** as Lead Auditor and a member of an Audit Team against the following reference documents):
 - ICHQ7A
 - ISO9001:2000,
 - ISO13485,
 - EU GMP Volume IV Parts 1 and 2,
 - OECD GLP,
 - Investigational Medicinal products Legislation
 - Providing **consulting services** in ISO9001:2008 implementation projects
 - 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).

1991-1999

- Held the position of QC Manager in a company producing veterinary vaccines using cell culture technology (Fort Dodge laboratories, Sligo, Ireland).

1989-1991

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- 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 FivePharma

Date	Address	Scope	# Days	Lead Auditor or Solo	Count
Jun-96	Ballina, Co Mayo, Ireland	Corporate Standards	1	Solo	1
May-01	Ballina, Co Mayo, Ireland	Corporate Standards	1	Solo	1
Aug-02	Wolfratshausen, Germany	Corporate Standards	2	Solo	1
				Sum	4
Jun-03	Zaragoza, Spain	EU GMP Volume 4 Part 1	1	Solo	1
Nov-03	Milan, Italy	EU GMP Volume 4 Part 2	1	Solo	1
Nov-03	Cais Cais, Portugal	EU GMP Volume 4 Part 1	1	Solo	1
Apr-04	Cork, Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Apr-04	Duiven, The Netherlands	EU GMP Volume 4 Part 1	1	Solo	1
Apr-04	Tallaght, Ireland	EU GMP Volume 4 Part 1	2	Solo	1
Jun-04	Shannon, Ireland	ISO17025	1	Solo	1
Jun-04	Athlone, Ireland	ISO17025	1	Solo	1
Oct-04	Newry, Ireland	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Nov-04	Ramdonksveer, Netherlands	EU GMP Volume 4 Part 1	1	Solo	1
				Sum	10
Jan-05	Athlone, Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Mar-05	Istanbul, Turkey	EU GMP Volume 4 Part 1	2	Solo	1
Mar-05	Heist, Belgium	EU GMP Volume 4 Part 2	5	Solo	1
May-05	Istanbul, Turkey	EU GMP Volume 4 Part 1	1	Solo	1
Jun-05	Newry, Ireland	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Nov-05	Boston, USA	EU GMP Volume 4 Part 1	1	Solo	1
Nov-05	Shannon, Ireland	ISO17025	1	Solo	1
Jun-05	Nenagh, Ireland	EU GMP Volume 4 Part 1	1	Lead Auditor	1
				Sum	8
Jan-06	Milan, Italy	EU GMP Volume 4 Part 2	1	Lead Auditor	1

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Feb-06	Sao Paulo	EU GMP Volume 4 Part 2	1	Lead Auditor	1
Feb-06	Sao Paulo	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Feb-06	Sao Paulo	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Feb-06	Taboa da Serra, Brazil	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Feb-06	Sao Paulo	EU GMP Volume 4 Part 1 Part 2	1	Lead Auditor	1
Mar-06	Ramdonksveer, Netherlands	EU GMP Volume 4 Part 1	1	Solo	1
Mar-06	Waterford, Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Apr-06	Razgrad, Bulgaria	EU GMP Volume 4 Part 2	1	Solo	1
May-06	Waterford, Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Jun-06	Dublin	PS9000	1	Solo	1
Jun-06	Germany	EU GMP Volume 4 Part 2	2	Solo	1
Jun-06	Mansfield, MA, 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	New Hampshire, USA	EU GMP Volume 4 Part 1	1	Solo	1
Jul-06	Raleigh, NC, USA	EU GMP Volume 4 Part 1	1	Solo	1
Jul-06	Ballinasloe, Ireland	PS9000	1	Solo	1
Oct-06	Berlin, Germany	EU GMP Volume 4 Part 2	1	Solo	1
Nov-06	Debrecen	EU GMP Volume 4 Part 2	1	Lead Auditor	1
Nov-06	Edinburgh, Scotland	EU GMP Volume 4 Part 2	1	Solo	1
Dec-06	Geel, Belgium	EU GMP Volume 4 Part 2	1	Solo	1
Dec-06	Milan, Italy	EU GMP Volume 4 Part 2	1	Lead Auditor	1
Dec-06	Clonmel, Ireland	ISO13485	2	Solo	1
				Sum	23
Jan-07	Athlone	EU GMP Volume 4 Part 1	1	Solo	1
Feb-07	Brighton UK	EU GMP Volume 4 Part 1	1	Solo	1
Feb-07	Hove UK	EU GMP Volume 4 Part 1	1	Solo	1
Mar-07	Dublin	GDP	1	Solo	1
Apr-07	Ramdonksveer, Netherlands	EU GMP Volume 4 Part 1	1	Solo	1

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Apr-07	Leverkusen, Germany	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Apr-07	Wuppertal Germany	EU GMP Volume 4 Part 2	1	Lead Auditor	1
May-07	Clonmel, Ireland	ISO 13485:2003 and CFR820	1	Solo	1
Jun-07	Waterford, Ireland	EU GMP Volume 4 Part 1	1	Solo	1
Jun-07	Sligo, Ireland	EU GMP Volume 4 Part 2	1	Solo	1
Jul-07	Corby UK	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Jul-07	Swindon UK	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Aug-07	Fuzhou, China	EU GMP Volume 4 Part 2	1	Solo	1
Aug-07	Shijiazhuang, China	EU GMP Volume 4 Part 2	1	Solo	1
Aug-07	Chengdu, China	EU GMP Volume 4 Part 2	1	Solo	1
Aug-07	Yantai, China	EU GMP Volume 4 Part 2	1	Solo	1
Aug-07	Yangzhou, China	EU GMP Volume 4 Part 2	1	Solo	1
Aug-07	Yangzhou, China	EU GMP Volume 4 Part 1	1	Solo	1
Sep-07	Wolfratshausen, Germany	EU GMP Volume 4 Part 1	1	Solo	1
Sep-07	Cologne Germany	EU GMP Volume 4 Part 2	1	Lead Auditor	1
Oct-07	Istanbul, Turkey	EU GMP Volume 4 Part 1	1	Solo	1
Dec-07	Manchester, UK	EU GMP Volume 4 Part 1	1	Lead Auditor	1
				Sum	22
Jan 08	Vancouver, Canada	Canadian Health Regulations	1	Solo	1
Feb 08	Schorndorf, Germany	EU GMP Volume 4 Part 1	1	Lead Auditor	1
Mar 08	Dorset, UK	EU GMP Volume 4 Part 2	1	Solo	1
June 08	Lyon, France	EU GMP Volume 4 Part 1	2	Lead Auditor	1
July 08	Toronto, Canada	EU GMP Volume 4 Part 1	1	Lead Auditor	1
July 08	Toronto, Canada	EU GMP Volume 4 Part 1	1	Lead Auditor	1
July 08	Craigavon, UK	EU GMP Volume 4 Part 1 Annex 13	1	Solo	1
Nov 08	Birmingham, UK	EU 94/C 63/03 GDP	1	Lead Auditor	1
Dec 08	Shijiazhuang, China	EU GMP Volume 4	2	Lead Auditor	1

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		Part 1			
Dec 08	Shijiazhuang, 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
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	The 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
				Sum	26
		Totals	110 Days		93 Audits

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Appendix 2

Table of Training delivered by Aidan Madden

#	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
15	Good Distribution Practices	Aidan Madden	Jan-06	Ireland	14
16	Good Distribution Practices	Aidan Madden	Jan-06	Ireland	18
17	Auditing LATP/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 LATP/GMP	Aidan Madden	Sep-06	Poland	10
22	Auditing LATP/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 LATP/GMP	Aidan Madden	Nov-06	UK	7
27	Good Distribution Practices	Aidan Madden	Nov-06	UK	8
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 LATP/GMP	Aidan Madden	Mar-07	UK	8

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32	Good Distribution Practices	Aidan Madden and Associates	Mar-07	UK	4
33	Internal Auditing	Aidan Madden	Apr-07	Ireland	7
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 LATP/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
41	Auditing LATP/GMP	Aidan Madden	Feb 08	UK	8
42	Good Distribution Practice	Aidan Madden and Associates	Mar 08	UK	12
43	Auditing LATP/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 2008	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 LATP/GMP	Aidan Madden	Nov 08	UK	8
53	Auditing LATP/GMP RSSL	Aidan Madden	Feb 09	UK	9
54	Good Distribution Practices	Aidan Madden	Mar 09	UK	12
55	Auditing LATP/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
				Total	1263