

Curriculum Vitae

Aidan Madden

March 2010

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 | 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 | Scotland | 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 | 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 |
| Dec 09 | Germany | EU GMP Volume 4 Part 2 | 2 | Lead | 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 |
| Feb 10 | Germany | ISO 9001:2008 | 1 | Auditor | 1 |

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|--------|-------|---------------------------|---------------------|------|-----------------------|
| Feb 10 | Italy | EU GMP Volume 4 Part 2 | 2 | Solo | 1 |
| | | | | | |
| | | | 6 | Sum | 5 |
| | | Totals | 128 Days | | 102 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 |
| | | | | sum | |
| 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 |
| | | | | sum | 587 |
| 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 |
| 34 | Good Distribution Practices | Aidan Madden and Associates | May-07 | Ireland | 9 |

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|----|-----------------------------|-----------------------------|-----------|-----------------|-----|
| 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 |
| | | | | 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 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 LAMP/GMP | Aidan Madden | Nov 08 | UK | 8 |
| | | | | 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 |
| 56 | Good Distribution Practices | Aidan Madden | Jun 09 | The Netherlands | 12 |
| 57 | Auditing | Aidan Madden | Jun 09 | Ireland | 24 |

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|----|------------------------------|-----------------------------|---------|--------------|-------------|
| 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 |
| | | | | 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 |
| | | | | Total | 1384 |