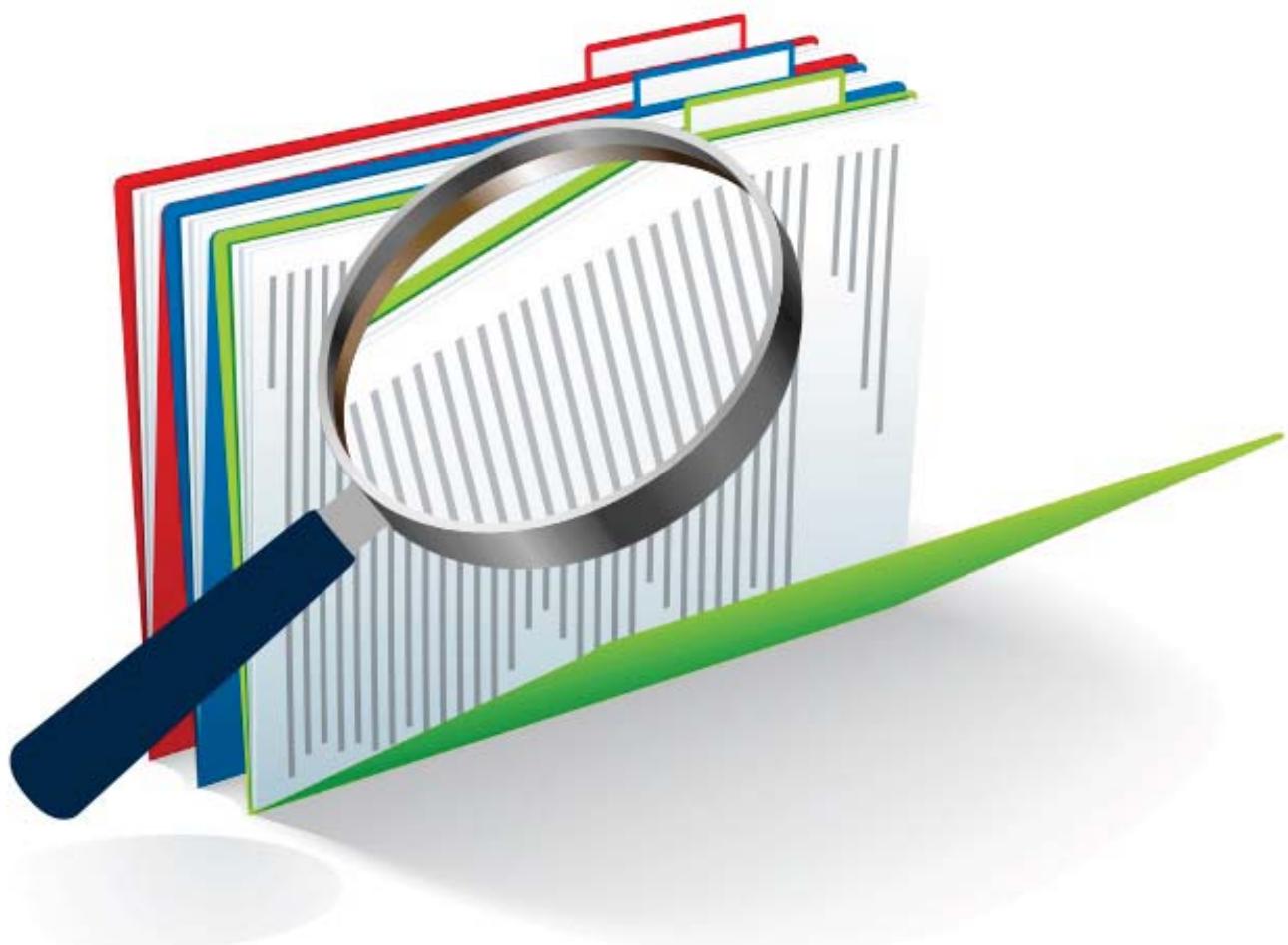# An Easy to Understand Guide
Good Documentation Practices (GDP)

PremierValidation LTD
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Good Documentation Practices

First Edition

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Forward by Mark Richardson

This book was born after many years of complaining about inconsistencies about the documentation practices that we encountered as a company both internally and externally. Being an organization that provides services to primarily biotech and pharmaceutical companies across the globe we found that it was nearly impossible to achieve a happy medium of understanding documentation across the board.

We have internal procedures, so did our clients, nothing was consistent and whilst everyone strived to be correct a lack of understanding would inevitably arise, things were questioned. Of course, we weren't adverse to things being challenged in the workplace – far from it and often (more often than not) when things were challenged they we proven to be already correct we still found that inconsistencies caused project delays.

A small group of us at Premier Validation decided that these inconsistencies could be replaced with consistencies and that our moaning could be replaced by happy chants of fulfilment if everyone (or at least a proportion of people in the industry) was singing from the same hymn sheet, or at least performing documentation entries in a consistent format that would be understood by our neighbours at home as easily as our cousins across the pond or from down-under; or even on Mars.

The moaning was replaced with buzzing as a new project was born; a small team of experts formed to develop the Premier Validation Good Documentation Practices (GDP) eBook, which has subsequently been transformed into this very book in your hands. This is a no-nonsense approach to performing handwritten entries into formal, regulated documentation; this non-fiction guide is useful for any regulated industry and for life in general. If nothing else, a tidy mind helps to keep a tidy, clutter-free life – something from which we all benefit.

The benefits of this book can even be felt outside of the office – even at home, when one makes notes a letter – "just in case" only to discover 5 years later when having a clear-out that: "Wait there, I wrote this – what on Earth (or Mars) does this actually mean? Is this a date, a reference number, a time for an appointment?" Sound familiar?

This book was written with the current regulations and practices of performing handwritten entries at the forefront of the content and I apologize now for any errors, omissions or for any content that is not longer current and if you find any of these I would be more than happy to hear from you, not least because you've taken the time to buy our very first book, but for the fact you've read my preface and if you've got this far I'm hoping I have at least made a half-decent effort, but all joking-aside we want this book to be successful and our readers to be happy with the content and all comments will be taken very seriously whether they're implemented or not.

Being our first book, we went around the houses a bit to get to a state that we felt that we had reached completion – our review, although structured and included many experts could have been tabled to flow a little more smoothly, a key lesson learned for the following software validation book that is due out in September 2010, we got there in the end (we think) and we hope that you will enjoy our book as much as we enjoyed putting it together and that enjoy the benefits as well as the read.

Acknowledgements

The position that we are currently in owes a lot of debt to Graham O'Keeffe, the driving force behind the book and without his eye for graphics, this book simply wouldn't be where it is today, also Darren Grant brought a great practical insight into the usage of the book from a user point of view that seen the removal of a lot of jargon and the simplification of many technical terms. Mark Richardson was instrumental in the streamlining of the content in conjunction with his objective reviewing based on a lifetime of applying such Good Documentation Practices within the industry.

A special thank-you to the original content author Don Hurd for the time and effort he put into producing the original transcript, although the whole team will agree that the finished product is very different now, it was Don who put the initial framework together capturing all of the critical elements.

Finally, we are also indebted to our graphic designer Louis Je Tonno and content author Anne-Marie Smith who went through the way the book was written and made it read with consistency, using a fine tooth-comb Anne-Marie meticulously went through our final draft and edited the language, tone and flow of the book to make it into the product that you're reading now.

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To Sum It Up