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Dr. Sharlin's Credentials

Dr. Sharlin's resume is at the end of this handout

Summary of Dr. Sharlin's Credentials

1. Former FDA statistical reviewer and reviewer that examined safety and efficacy
2. Over 20 years of industrial strength software development and database experience building large-scale information systems for pharmaceutical, government and commercial clients.
3. Improved the structure and content of submissions to reduce FDA approval time
4. Trained thousands of people from hundreds of pharmaceutical companies in software development, validation, statistical analysis, regulatory affairs, CTD, e-sub and Part 11 compliance
5. Provided consulting support to drug, device and biologics firms for over nine years