Improving and Accelerating Therapeutic Development for Nervous System Disorders is the summary of a workshop convened by the IOM Forum on Neuroscience and Nervous System Disorders to examine opportunities to accelerate early phases of drug development for nervous system drug discovery. Workshop participants discussed challenges in neuroscience research for enabling faster entry of potential treatments into first-in-human trials, explored how new and emerging tools and technologies may improve the efficiency of research, and considered mechanisms to facilitate a more effective and efficient development pipeline. There are several challenges to the current drug development pipeline for nervous system disorders. The fundamental etiology and pathophysiology of many nervous system disorders are unknown and the brain is inaccessible to study, making it difficult to develop accurate models. Patient heterogeneity is high, disease pathology can occur years to decades before becoming clinically apparent, and diagnostic and treatment biomarkers are lacking. In addition, the lack of validated targets, limitations related to the predictive validity of animal models - the extent to which the model predicts clinical efficacy - and regulatory barriers can also impede translation and drug development for nervous system disorders. Improving and Accelerating Therapeutic Development for Nervous System Disorders identifies avenues for moving directly from cellular models to human trials, minimizing the need for animal models to test efficacy, and discusses the potential benefits and risks of such an approach. This report is a timely discussion of opportunities to improve early drug development with a focus toward preclinical trials.

A guide to writing computer code covers such topics as variable
naming, presentation style, error handling, and security.

Principles of Parenteral Solution Validation: A Practical Lifecycle Approach covers all aspects involved in the development and process validation of a parenteral product. By using a lifecycle approach, this book discusses the latest technology, compliance developments, and regulatory considerations and trends, from process design, to divesting. As part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin, this book incorporates numerous case studies and real-world examples that address timely problems and offer solutions to the daily challenges facing practitioners in this area. Discusses international and domestic regulatory considerations in every section Features callout boxes that contain points-of-interest for each segment of the audience so readers can quickly find their interests and needs Contains important topics, including risk management, the preparation and execution of properly designed studies, scale-up and technology transfer activities, problem-solving, and more

Risk model validation is an emerging and important area of research, and has arisen because of Basel I and II. These regulatory initiatives require trading institutions and lending institutions to compute their reserve capital in a highly analytic way, based on the use of internal risk models. It is part of the regulatory structure that these risk models be validated both internally and externally, and there is a great shortage of information as to best practise. Editors Christodoulakis and Satchell collect papers that are beginning to appear by regulators, consultants, and academics, to provide the first collection that focuses on the quantitative side of model validation. The book covers the three main areas of risk: Credit Risk and Market and Operational Risk. *Risk model validation is a requirement of Basel I and II *The first collection of papers in this new and developing area of research *International authors cover model validation in credit, market, and operational risk

This study reviews two decades of research on mental disorder and presents empirical and theoretical work which aims to determine more accurate predictions of violent behaviour.

The estimation and the validation of the Basel II risk parameters PD (default probability), LGD (loss given fault), and EAD (exposure at default) is an important problem in banking practice. These parameters are used on the one hand as inputs to credit portfolio models and in loan pricing frameworks, on the other to compute regulatory capital according to the new Basel rules. This book covers the state-of-the-art in designing and validating rating systems and default probability estimations. Furthermore, it presents techniques to estimate LGD and EAD and includes a chapter on stress testing of the Basel II risk parameters. The second edition is extended by three chapters explaining how the Basel II risk parameters can be used for building a framework for risk-adjusted pricing and risk management of loans.

During the preschool age, children acquire a rapid increase in intellectual ability, social development, and complexity in language. Along with this revolutionary change, some children begin to confront with parents, experience jealousy and develop sense of guilt. Behavioural abnormalities manifest when children externalize these difficulties resulting aggression, delinquent behaviour, autism and temper tantrums and are at a greater risk of developing psychiatric disorder in later life. These disorders have
a very good prognosis if treated at the onset. Therefore, these disorders must be identified early and referred to appropriate care. Because parents and health care workers do not have ability to identify behavioural problems at an early stage, most children are referred at an advanced stage of the disease. Therefore, a simple, sensitive and relatively inexpensive screening instrument that can be used routinely is essential to identify these problems in the community. This book focuses on developing and validating such screening instrument that could be used to screen behavioural problems of preschool children.

In the Fourth Edition of Scale Development, Robert F. DeVellis demystifies measurement by emphasizing a logical rather than strictly mathematical understanding of concepts. The text supports readers in comprehending newer approaches to measurement, comparing them to classical approaches, and grasping more clearly the relative merits of each. This edition addresses new topics pertinent to modern measurement approaches and includes additional exercises and topics for class discussion. Available with Perusall—an eBook that makes it easier to prepare for class Perusall is an award-winning eBook platform featuring social annotation tools that allow students and instructors to collaboratively mark up and discuss their SAGE textbook. Backed by research and supported by technological innovations developed at Harvard University, this process of learning through collaborative annotation keeps your students engaged and makes teaching easier and more effective. Learn more.

Integrating care across disciplines and organisations around the needs of the person with diabetes has been proposed as an approach that could improve care while reducing cost- but has it and can it? Integrated Diabetes Care- A Multidisciplinary Approach collates evidence of worldwide approaches to both horizontal integration (across disciplines) and vertical integration (across organizations) in diabetes care and describe what was done, what worked and what appeared to be the barriers to achieving the goals of the programmes. Evidence is sought from groups who have developed different approaches to integrating diabetes care in different health systems (eg insurance vs tax payer funded, single vs multiple organization, published vs unpublished). A final chapter brings the evidence together for a final discussion about what seems to work and what does not.

For the past decade, process validation issues ranked within the top six of Food and Drug Administration (FDA) form 483 observation findings issued each year. This poses a substantial problem for the medical device industry and is the reason why the authors wanted to write this book. The authors will share their collective knowledge: to help organizations improve patient safety and increase profitability while maintaining a state of compliance with regulations and standards. The intent of this book is to provide manufacturing quality professionals working in virtually any industry a quick, convenient, and comprehensive guide to properly conduct process validations that meet regulatory and certification requirements. It will aid quality technicians, engineers, managers, and others that need to plan, conduct, and monitor validation activities.

Pharmaceutical Computer Validation Introduction gives you a comprehensive introduction to computer systems validation as the computers come to life while the head of computer systems
Development And Validation Of Risk Prediction Model For

at a pharmaceutical company has to prepare for an FDA inspection. You will learn about regulations, the personnel responsible for computer validation, how to accomplish validation, examples of regulatory problems, and so on. It is also relevant for the medical device, food, and cosmetic industries. 86 pages in the guide include a handy printout of several relevant FDA documents. Those readers who wish to have an accompanying program with video and interactivity should also purchase the CD version.

As our nation enters a new era of medical science that offers the real prospect of personalized health care, we will be confronted by an increasingly complex array of health care options and decisions. The Learning Healthcare System considers how health care is structured to develop and to apply evidence-from health profession training and infrastructure development to advances in research methodology, patient engagement, payment schemes, and measurement-and highlights opportunities for the creation of a sustainable learning health care system that gets the right care to people when they need it and then captures the results for improvement. This book will be of primary interest to hospital and insurance industry administrators, health care providers, those who train and educate health workers, researchers, and policymakers. The Learning Healthcare System is the first in a series that will focus on issues important to improving the development and application of evidence in health care decision making. The Roundtable on Evidence-Based Medicine serves as a neutral venue for cooperative work among key stakeholders on several dimensions: to help transform the availability and use of the best evidence for the collaborative health care choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and, ultimately, to ensure innovation, quality, safety, and value in health care.

Handbook of Analytical Quality by Design addresses the steps involved in analytical method development and validation in an effort to avoid quality crises in later stages. The AQbD approach significantly enhances method performance and robustness which are crucial during inter-laboratory studies and also affect the analytical lifecycle of the developed method. Sections cover sample preparation problems and the usefulness of the QbD concept involving Quality Risk Management (QRM), Design of Experiments (DoE) and Multivariate (MVT) Statistical Approaches to solve by optimizing the developed method, along with validation for different techniques like HPLC, UPLC, UFLC, LC-MS and electrophoresis. This will be an ideal resource for graduate students and professionals working in the pharmaceutical industry, analytical chemistry, regulatory agencies, and those in related academic fields. Concise language for easy understanding of the novel and holistic concept Covers key aspects of analytical development and validation Provides a robust, flexible, operable range for an analytical method with greater excellence and regulatory compliance

Cancer is clearly an age-related disease. Recent research in both aging and cancer has demonstrated the complex interaction between the two phenomena. This affects a wide spectrum of research and practice, anywhere from basic research to health care organization. Core examples of these close associations are addressed in this book. Starting with basic research, the first chapters cover cancer development, mTOR inhibition, senescent
cells altering the tumor microenvironment, and immune senescence affecting cancer vaccine response. Taking into account the multidisciplinarity of geriatric oncology, several chapters focus on geriatric and oncologic aspects in patient assessment, treatment options, nursing and exercise programs. The book is rounded off by a discussion on the impact of the metabolic syndrome illustrating the interactions between comorbidity and cancer and a chapter on frailty. This book provides the reader with insights that will hopefully foster his or her reflection in their own research and practice to further the development of this most exciting field. Given the aging of the population worldwide and the high prevalence of cancer, it is essential reading not only for oncologists and geriatricians but for all health practitioners.

Thoroughly revised to include the latest industry developments, the Second Edition presents a comprehensive overview of computer validation and verification principles and how to put them into practice. To provide the current best practice and guidance on identifying and implementing improvements for computer systems, the text extensively reviews r

Abstract: “Software project managers need tools to estimate and track project goals in a continuous fashion before, during, and after development of a system. In a edition, they need an ability to compare the current project status with past project profiles to validate management intuition, identify problems, and then direct appropriate resources to the sources of problems. This paper describes a measurement-based approach to calculating the risk inherent in meeting project goals that leverages past project metrics and existing estimation and tracking models. We introduce the IV & V Goal/Questions/Metrics model. explain its use in the software development life cycle, and describe our attempts to validate the model through the reverse engineering of existing projects.

This book provides a state-of-the-art look at the applied biomechanics of accidental injury and prevention. The editors, Drs. Narayan Yoganandan, Alan M. Nahum and John W. Melvin are recognized international leaders and researchers in injury biomechanics, prevention and trauma medicine. They have assembled renowned researchers as authors for 29 chapters to cover individual aspects of human injury assessment and prevention. This third edition is thoroughly revised and expanded with new chapters in different fields. Topics covered address automotive, aviation, military and other environments. Field data collection; injury coding/scaling; injury epidemiology; mechanisms of injury; human tolerance to injury; simulations using experimental, complex computational models (finite element modeling) and statistical processes; anthropomorphic test device design, development and validation for crashworthiness applications in topics cited above; and current regulations are covered. Risk functions and injury criteria for various body regions are included. Adult and pediatric populations are addressed. The exhaustive list of references in many areas along with the latest developments is valuable to all those involved or intend to pursue this important topic on human injury biomechanics and prevention. The expanded edition will interest a variety of scholars and professionals including physicians, biomedical researchers in many disciplines, basic scientists, attorneys and jurists involved in accidental injury cases and governmental bodies. It is hoped that this book will foster
multidisciplinary collaborations by medical and engineering researchers and academicians and practicing physicians for injury assessment and prevention and stimulate more applied research, education and training in the field of accidental-injury causation and prevention.

Here are the first book written specifically to help medical device and software engineers, QA and compliance professionals, and corporate business managers better understand and implement critical verification and validation processes for medical device software. Offering you a much broader, higher-level picture than other books in this field, this book helps you think critically about software validation — to build confidence in your software and its safety and effectiveness. The book presents validation activities for each phase of the development lifecycle and shows: why these activities are important and add value; how to undertake them; and what outputs need to be created to document the validation process. From software embedded within medical devices, to software that performs as a medical device itself, this comprehensive book explains how properly handled validation throughout the development lifecycle can help bring medical devices to completion sooner, at higher quality, in compliance with regulations.

Practical approaches to ensure that analytical methods and instruments meet GMP standards and requirements Complementing the authors' first book, Analytical Method Validation and Instrument Performance Verification, this new volume provides coverage of more advanced topics, focusing on additional and supplemental methods, instruments, and electronic systems that are used in pharmaceutical, biopharmaceutical, and clinical testing. Readers will gain new and valuable insights that enable them to avoid common pitfalls in order to seamlessly conduct analytical method validation as well as instrument operation qualification and performance verification. Part 1, Method Validation, begins with an overview of the book's risk-based approach to phase appropriate validation and instrument qualification; it then focuses on the strategies and requirements for early phase drug development, including validation of specific techniques and functions such as process analytical technology, cleaning validation, and validation of laboratory information management systems. Part 2, Instrument Performance Verification, explores the underlying principles and techniques for verifying instrument performance — coverage includes analytical instruments that are increasingly important to the pharmaceutical industry, such as NIR spectrometers and particle size analyzers — and offers readers a variety of alternative approaches for the successful verification of instrument performance based on the needs of their labs. At the end of each chapter, the authors examine important practical problems and share their solutions. All the methods covered in this book follow Good Analytical Practices (GAP) to ensure that reliable data are generated in compliance with current Good Manufacturing Practices (cGMP). Analysts, scientists, engineers, technologists, and technical managers should turn to this book to ensure that analytical methods and instruments are accurate and meet GMP standards and requirements.

Effective risk management is essential for the success of large projects built and operated by the Department of Energy (DOE), particularly for the one-of-a-kind projects that characterize much of its mission. To enhance DOE's risk management efforts, the de-
department asked the NRC to prepare a summary of the most effective practices used by leading owner organizations. The study's primary objective was to provide DOE project managers with a basic understanding of both the project owner's risk management role and effective oversight of those risk management activities delegated to contractors.

How to Validate a Pharmaceutical Process provides a “how to approach to developing and implementing a sustainable pharmaceutical process validation program. The latest volume in the Expertise in Pharmaceutical Process Technology Series, this book illustrates the methods and reasoning behind processes and protocols. It also addresses practical problems and offers solutions to qualify and validate a pharmaceutical process. Understanding the “why is critical to a successful and defensible process validation, making this book an essential research companion for all practitioners engaged in pharmaceutical process validation. Thoroughly referenced and based on the latest research and literature illustrates the most common issues related to developing and implementing a sustainable process validation program and provides examples on how to be successful Covers important topics such as the lifecycle approach, quality by design, risk assessment, critical process parameters, US and international regulatory guidelines, and more

Absolute Risk: Methods and Applications in Clinical Management and Public Health provides theory and examples to demonstrate the importance of absolute risk in counseling patients, devising public health strategies, and clinical management. The book provides sufficient technical detail to allow statisticians, epidemiologists, and clinicians to build, test, and apply models of absolute risk. Features: Provides theoretical basis for modeling absolute risk, including competing risks and cause-specific and cumulative incidence regression Discusses various sampling designs for estimating absolute risk and criteria to evaluate models Provides details on statistical inference for the various sampling designs Discusses criteria for evaluating risk models and comparing risk models, including both general criteria and problem-specific expected losses in well-defined clinical and public health applications Describes many applications encompassing both disease prevention and prognosis, and ranging from counseling individual patients, to clinical decision making, to assessing the impact of risk-based public health strategies Discusses model updating, family-based designs, dynamic projections, and other topics Ruth M. Pfeiffer is a mathematical statistician and Fellow of the American Statistical Association, with interests in risk modeling, dimension reduction, and applications in epidemiology. She developed absolute risk models for breast cancer, colon cancer, melanoma, and second primary thyroid cancer following a childhood cancer diagnosis. Mitchell H. Gail developed the widely used “Gail model” for projecting the absolute risk of invasive breast cancer. He is a medical statistician with interests in statistical methods and applications in epidemiology and molecular medicine. He is a member of the National Academy of Medicine and former President of the American Statistical Association. Both are Senior Investigators in the Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health.

Sets forth tested and proven risk management practices in drug manufacturing Risk management is essential for safe and effi-
cient pharmaceutical and biopharmaceutical manufacturing, control, and distribution. With this book as their guide, readers involved in all facets of drug manufacturing have a single, expertly written, and organized resource to guide them through all facets of risk management and analysis. It sets forth a solid foundation in risk management concepts and then explains how these concepts are applied to drug manufacturing. Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing features contributions from leading international experts in risk management and drug manufacturing. These contributions reflect the latest research, practices, and industry standards as well as the authors' firsthand experience. Readers can turn to the book for: Basic foundation of risk management principles, practices, and applications Tested and proven tools and methods for managing risk in pharmaceutical and biopharmaceutical product manufacturing processes Recent FDA guidelines, EU regulations, and international standards governing the application of risk management to drug manufacturing Case studies and detailed examples demonstrating the use and results of applying risk management principles to drug product manufacturing. Bibliography and extensive references leading to the literature and helpful resources in the field. With its unique focus on the application of risk management to biopharmaceutical and pharmaceutical manufacturing, this book is an essential resource for pharmaceutical and biopharmaceutical manufacturing facilities must have a clear understanding of current good manufacturing practice (cGMP) and preapproval inspection (PAI) requirements. Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments provides up-to-date coverage of aseptic processing techniques and sterilization methods. Written by a recognized expert with more than 20 years of industry experience in aseptic manufacturing, this practical resource illustrates a comprehensive approach to sterile manufacturing engineering that can achieve drug manufacturing objectives and goals. Topics include sanitary piping and equipment, cleaning and manufacturing process validation, computerized automated systems, personal protective equipment (PPE), clean-in-place (CIP) systems, barriers and isolators, and guidelines for statistical procedure. Offering authoritative guidance on the key aspects of sterile manufacturing engineering, this volume: Covers fundamentals of aseptic techniques, quality by design, risk assessment and management, and operational requirements. Addresses various regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH. Provides techniques for systematic process optimization and good manufacturing practice. Emphasizes the importance of attention to detail in process development and validation. Features real-world examples highlighting different aspects of drug manufacturing. Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments is an indispensable reference and guide for all chemists, chemical engineers, pharmaceutical professionals and
engineers, and other professionals working in pharmaceutical sciences and manufacturing.

Turn Innovative Ideas into Products and Services—and Manage and Control Them Using Project Management Tools The first book to integrate project management and product development, Project Management in New Product Development shows you how to manage the translation of ideas into new products and services and get them to market cheaper, better, and faster using advanced project management tools and techniques. Packed with detailed case studies and illustrations, this unique book explains how to move new products and services quickly from concept to product to market as a managed and seamless process free of problems and delays. This project tool also shows how to ensure that bad products are stopped at gateway points, before they become product and project failures. Project Management in New Product Development features: The first integrated treatment of project management and new product development designed for modern, globally oriented firms Numerous case studies covering software, technology, electronics, construction, telecommunications, military, and aerospace 150 informative tables, figures, and graphics

In examining the relationship between nutritional exposure and disease aetiology, the importance of a carefully considered experimental design cannot be overstated. A sound experimental design involves the formulation of a clear research hypothesis and the identification of appropriate measures of exposure and outcome. It is essential that these variables can be measured with a minimum of error, whilst taking into account the effects of chance and bias, and being aware of the risk of confounding variables. The first edition of Design Concepts in Nutritional Epidemiology presented a thorough guide to research methods in nutritional epidemiology. Since publication of the 1st edition, we now have a much better understanding of the characteristics of nutritional exposure that need to be measured in order to answer questions about diet-disease relationships. The 2nd edition has been extensively revised to include the most up-to-date methods of researching this relationship. Included are new chapters on qualitative and sociological measures, anthropometric measures, gene-nutrient interactions, and cross-sectional studies. Design Concepts in Nutritional Epidemiology will be an essential text for nutritionists and epidemiologists, helping them in their quest to improve the quality of information upon which important public health decisions are made.

Develop Effective Immunogenicity Risk Mitigation Strategies Immunogenicity assessment is a prerequisite for the successful development of biopharmaceuticals, including safety and efficacy evaluation. Using advanced statistical methods in the study design and analysis stages is therefore essential to immunogenicity risk assessment and mitigation strategies. Statistical Methods for Immunogenicity Assessment provides a single source of information on statistical concepts, principles, methods, and strategies for detection, quantification, assessment, and control of immunogenicity. The book first gives an overview of the impact of immunogenicity on biopharmaceutical development, regulatory requirements, and statistical methods and strategies used for immunogenicity detection, quantification, and risk assessment and mitigation. It then covers anti-drug antibody (ADA) assay develop-
Development And Validation Of Risk Prediction Model For Immunogenicity

ment, optimization, validation, and transfer as well as the analysis of cut point, a key assay performance parameter in ADA assay development and validation. The authors illustrate how to apply statistical modeling approaches to establish associations between ADA and clinical outcomes, predict immunogenicity risk, and develop risk mitigation strategies. They also present various strategies for immunogenicity risk control. The book concludes with an explanation of the computer codes and algorithms of the statistical methods. A critical issue in the development of biologics, immunogenicity can cause early termination or limited use of the products if not managed well. This book shows how to use robust statistical methods for detecting, quantifying, assessing, and mitigating immunogenicity risk. It is an invaluable resource for anyone involved in immunogenicity risk assessment and control in both non-clinical and clinical biopharmaceutical development.

Engineering and Food for the 21st Century presents important reviews and up-to-date discussions of major topics relating to engineering and food. Internationally renowned contributors discuss a broad base of food engineering and related subjects, including research and prospective industrial applications. The first part begins with recent trends in food engineering and challenges for the future. It then presents important discussions of fundamental aspects of food engineering, including physical chemistry, mass transfer, food rheology, and food structure. Part 2 contains state-of-the-art presentations on thermal processing and packaging, minimal processing, emerging technologies, process control, biotechnology, and environmental factors associated with the processing of food.

The second edition of this volume provides insight and practical illustrations on how modern statistical concepts and regression methods can be applied in medical prediction problems, including diagnostic and prognostic outcomes. Many advances have been made in statistical approaches towards outcome prediction, but a sensible strategy is needed for model development, validation, and updating, such that prediction models can better support medical practice. There is an increasing need for personalized evidence-based medicine that uses an individualized approach to medical decision-making. In this Big Data era, there is expanded access to large volumes of routinely collected data and an increased number of applications for prediction models, such as targeted early detection of disease and individualized approaches to diagnostic testing and treatment. Clinical Prediction Models presents a practical checklist that needs to be considered for development of a valid prediction model. Steps include preliminary considerations such as dealing with missing values; coding of predictors; selection of main effects and interactions for a multivariable model; estimation of model parameters with shrinkage methods and incorporation of external data; evaluation of performance and usefulness; internal validation; and presentation formatting. The text also addresses common issues that make prediction models suboptimal, such as small sample sizes, exaggerated claims, and poor generalizability. The text is primarily intended for clinical epidemiologists and biostatisticians. Including many case studies and publicly available R code and data sets, the book is also appropriate as a textbook for a graduate course on predictive modeling in diagnosis and prognosis. While practical in nature, the book also provides a philosophical perspective on da-
ta analysis in medicine that goes beyond predictive modeling. Updates to this new and expanded edition include: • A discussion of Big Data and its implications for the design of prediction models • Machine learning issues • More simulations with missing ‘y’ values • Extended discussion on between-cohort heterogeneity • Description of ShinyApp • Updated LASSO illustration • New case studies

IFRS 9 and CECL Credit Risk Modelling and Validation covers a hot topic in risk management. Both IFRS 9 and CECL accounting standards require Banks to adopt a new perspective in assessing Expected Credit Losses. The book explores a wide range of models and corresponding validation procedures. The most traditional regression analyses pave the way to more innovative methods like machine learning, survival analysis, and competing risk modelling. Special attention is then devoted to scarce data and low default portfolios. A practical approach inspires the learning journey. In each section the theoretical dissertation is accompanied by Examples and Case Studies worked in R and SAS, the most widely used software packages used by practitioners in Credit Risk Management. Offers a broad survey that explains which models work best for mortgage, small business, cards, commercial real estate, commercial loans and other credit products

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in

This handbook provides the most up to date resource currently available for interpreting and understanding design controls. This handbook is the most exhaustive resource ever written about FDA & ISO 13485 design controls for medical devices with a collection of all applicable regulations and real-world examples. Four-hundred & forty, 8.5" X 11" pages provides an extensive evaluation of FDA 21 CFR 820 and is cross-referenced with ISO 13485 to provide readers with a broad and in-depth review of practical design control implementation techniques. This handbook also covers basic, intermediate and advanced design control topics and is an ideal resource for implementing new design control processes or upgrading an existing process into medical device quality systems. This critical resource also specifically outlines key topics which will allow quality managers and medical device developers to improve compliance quickly to pass internal and external audits and FDA inspections. The author breaks down the regulation line by line and provides a detailed interpretation by using supportive evidence from the FDA design control guidance and the quality systems preamble. Numerous examples, case studies, best practices, 70+ figures and 45+ tables provide practical implementation techniques which are based on the author’s extensive experience launching numerous medical device products and by integrating industry consultant expertise. In addition, bonus chapters include: explanation of medical device classification, compliance to design controls, risk management, and the design control quality system preamble. 20-40 pages are dedi-
cated to each of the major design control topics: Design and Development Planning, Design Input, Design Output, Design Transfer, Design Verification, Design Validation, Design Change and Design History File.

There is growing recognition that sexual offending is a multi-determined phenomenon requiring a multi-disciplinary perspective. The significant contribution of psychology and psychiatry, but also sociology, gender studies and anthropology to the study of sex offending and perpetrators of sex offenses has played a key role in the development of a distinct field of research. In recent years, however, there has been an increase in criminological research on the topic, introducing criminological theory and concepts, scientific evidence and observations, and new methodologies to the field. This book brings together international leading scholars to consider key topics on sex offending and, where possible, compare and contrast criminological viewpoints with those of other disciplines, such as psychology and psychiatry. This book considers the following questions: Are the key explanatory factors of sex offenses completely distinct and different from those of non-sex crime and delinquency? Are current models explaining adult sex offending also applicable to explain sex crimes on college campuses, female sex offending, sexual exploitation, sexual homicide, or child luring over the internet? Are today’s youth involved in sex offenses tomorrow’s adult perpetrators of sex crimes? What is the risk of sexual recidivism and are risk assessment tools effective to identify individuals at-risk of committing another sex crime in the future? Are current legal measures used to prevent sex crimes effective? What are the known effects of such measures? What are the issues and challenges related to the criminal investigation of sex offenses? This book is essential reading for students and researchers from disciplines such as criminology, psychiatry, psychology, sexology, social work and sociology, as well as criminal justice professionals and practitioners such as police investigators, prosecutors, judges, probation/parole officers, and treatment providers/counsellors involved with individuals having perpetrated sex offenses.

This book provides a unique, focused introduction to the analytical skills, methods and techniques in the assessment of credit risk that are necessary to tackle and analyze complex credit problems. It employs models and techniques from operations research and management science to investigate more closely risk models for applications within the banking industry and in financial markets. Furthermore, the book presents the advances and trends in model development and validation for credit scoring/rating, the recent regulatory requirements and the current best practices. Using examples and fully worked case applications, the book is a valuable resource for advanced courses in financial risk management, but also helpful to researchers and professionals working in financial and business analytics, financial modeling, credit risk analysis, and decision science.

This open access book comprehensively covers the fundamentals of clinical data science, focusing on data collection, modelling and clinical applications. Topics covered in the first section on data collection include: data sources, data at scale (big data), data stewardship (FAIR data) and related privacy concerns. Aspects of predictive modelling using techniques such as classification, regression or clustering, and prediction model validation will be cov-
ered in the second section. The third section covers aspects of (mobile) clinical decision support systems, operational excellence and value-based healthcare. Fundamentals of Clinical Data Science is an essential resource for healthcare professionals and IT consultants intending to develop and refine their skills in personalized medicine, using solutions based on large datasets from electronic health records or telemonitoring programmes. The book’s promise is “no math, no code” and will explain the topics in a style that is optimized for a healthcare audience.