

Good Clinical Practice: A Question & Answer Reference Guide

May 2010

Edited by
Mark P. Mathison
PAREXEL International Corporation

**Including Answers to Hundreds of
Frequently Asked Questions, Plus**

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- ICH Consolidated Good Clinical Practice Guideline (E6)
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- European Union Clinical Trials Directive
- European Union Good Clinical Practice Directive

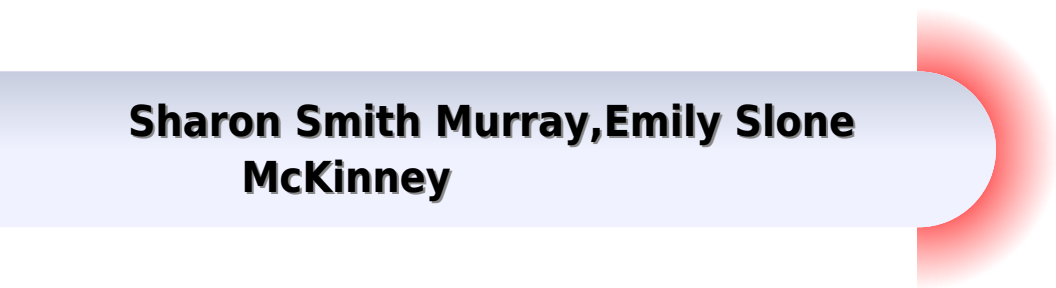


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2010 GOOD CLINICAL PRACTICE:
A QUESTION & ANSWER
REFERENCE GUIDE

Good Clinical Practice A Question Answer Reference Guide May 2010

**Sharon Smith Murray, Emily Slone
McKinney**



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Human Subjects Research after the Holocaust Sheldon Rubenfeld, Susan Benedict, 2014-06-30 An engaging compelling and disturbing confrontation with evil a book that will be transformative in its call for individual and collective moral responsibility Michael A Grodin M D Professor and Director Project on Medicine and the Holocaust Elie Wiesel Center for Judaic Studies Boston University Human Subjects Research after the Holocaust challenges you to confront the misguided medical ethics of the Third Reich personally and to apply the lessons learned to contemporary human subjects research While it is comforting to believe that Nazi physicians nurses and bioscientists were either incompetent mad or few in number they were in fact the best in the world at the time and the vast majority participated in the government program of applied biology They were not coerced to behave as they did they enthusiastically exploited widely accepted eugenic theories to design horrendous medical experiments gas chambers and euthanasia programs which ultimately led to mass murder in the concentration camps Americans provided financial support for their research modeled their medical education and research after the Germans and continued to perform unethical human subjects research even after the Nuremberg Doctors Trial The German Medical Association apologized in 2012 for the behavior of its physicians during the Third Reich By examining the medical crimes of human subjects researchers during the Third Reich you will naturally examine your own behavior and that of your colleagues and perhaps ask yourself If the best physicians and bioscientists of the early 20th century could do evil while believing they were doing good can I be certain that I will never do the same *Good Clinical Practice* Munish Mehra, 2009 **FDA Regulatory Affairs** David Mantus, Douglas J. Pisano, 2014-02-28 FDA Regulatory Affairs is a roadmap to prescription drug biologics and medical device development in the United States Written in plain English the concise and jargon free text demystifies the inner workings of the US Food and Drug Administration FDA and facilitates an understanding of how the agency operates with respect to compliance and product approval including clinical trial exemptions fast track status advisory committee procedures and more The Third Edition of this highly successful publication Examines the harmonization of the US Federal Food Drug and Cosmetic Act with international regulations on human drug biologics and device development research manufacturing and marketing Includes contributions from experts at organizations such as the FDA National Institutes of Health NIH and PAREXEL Focuses on the new drug application NDA process cGMPs GCPs quality system compliance and corresponding documentation requirements Provides updates to the FDA Safety and Innovation Act FDASIA incorporating pediatric guidelines and follow on biologics regulations from the 2012 Prescription Drug User Fee Act PDUFA V Explains current FDA inspection processes enforcement options and how to handle FDA meetings and required submissions Co edited by an industry leader Mantus and a respected academic Pisano FDA Regulatory Affairs Third Edition delivers a compilation of the selected US laws and regulations as well as a straightforward commentary on the FDA product approval process that s broadly useful to both business and academia **Ensuring the Integrity of Electronic Health**

Records Orlando López, 2020-12-21 Data integrity is a critical aspect to the design implementation and usage of any system which stores processes or retrieves data The overall intent of any data integrity technique is the same ensure data is recorded exactly as intended and upon later retrieval ensure the data is the same as it was when originally recorded Any alteration to the data is then traced to the person who made the modification The integrity of data in a patient's electronic health record is critical to ensuring the safety of the patient This book is relevant to production systems and quality control systems associated with the manufacture of pharmaceuticals and medical device products and updates the practical information to enable better understanding of the controls applicable to e records The book highlights the e records suitability implementation and associated risk assessed controls and e records handling The book also provides updated regulatory standards from global regulatory organizations such as MHRA Medicines and Healthcare Products Regulatory Agency UK FDA Food and Drug Administration US National Medical Products Association China TGA Therapeutic Goods Administration Australia SIMGP Russia State Institute of Medicines and Good Practices and the World Health Organization to name a few

Medical-Surgical Nursing - E-Book Donna D. Ignatavicius, M. Linda Workman, 2013-12-27 Using a uniquely collaborative and reader friendly approach expert authors Donna D Ignatavicius and M Linda Workman cover all the latest trends evidence based treatment guidelines and additional updated information needed for safe clinical practice in medical surgical nursing This seventh edition features an expanded emphasis on patient safety and NCLEX Examination preparation new ties to the QSEN priorities for patient safety and a greater alignment with the language and focus of clinical practice A new chapter on evidence based practice and a wealth of effective online learning tools help solidify your mastery of medical surgical nursing UNIQUE Collaborative approach presents all medical surgical nursing and other interventions through the lens of the nursing process Reader friendly direct writing style makes this one of the most readable medical surgical nursing textbooks available UNIQUE Cutting edge focus on the latest trends in nursing practice and nursing education prepares you for both today and tomorrow's nursing practice UNIQUE Integrated tools for NCLEX preparation get you ready for your licensure examination Chapter opening Learning Outcomes are linked to Self Assessment Questions for the NCLEX Examination on the Evolve website Unique chapter ending Get Ready for the NCLEX Examination sections include Key Points organized by NCLEX Client Needs Categories UNIQUE Focus on nursing concepts helps bridge the gap between the concepts learned in Nursing Fundamentals and disorders content learned in the medical surgical nursing course UNIQUE Emphasis on clinical decision making teaches you to apply concepts to true to life clinical situations UNIQUE Concentration on the core body of knowledge for the RN level of medical surgical nursing practice focuses your attention on need to know content to pass the NCLEX Examination and practice safely as a beginning nurse Rich array of effective learning aids includes Best Practice for Patient Safety Quality Care Best Practice for Emergency Care Patient and Family Education Preparing for Self Management Nursing Focus on the Older Adult Home Care Assessment Focused Assessment

Common Examples of Drug Therapy Evidence Based Practice Concept Maps Laboratory Profiles Assessment Using Gordon's Functional Health Patterns *Rosen's Emergency Medicine - Concepts and Clinical Practice E-Book* Ron Walls, Robert Hockberger, Marianne Gausche-Hill, 2017-03-09 Since its revolutionary first edition in 1983 Rosen's Emergency Medicine set the standard for reliable accessible and comprehensive information to guide the clinical practice of emergency medicine. Generations of emergency medicine residents and practitioners have relied on Rosen's as the source for current information across the spectrum of emergency medicine practice. The 9th Edition continues this tradition of excellence offering the unparalleled clarity and authority you've come to expect from the award winning leader in the field. Throughout the text content is now more concise clinically relevant and accessible than ever before meeting the needs of today's increasingly busy emergency medicine practitioner. Delivers clear precise information focused writing and references relevant concise information and generous use of illustrations provide definitive guidance for every emergency situation. Offers the most immediately relevant content of any emergency medicine reference providing diagnostic and treatment recommendations with clear indications and preferred actions. Presents the expertise and knowledge of a new generation of editors who bring fresh insights and new perspectives to the table. Includes more than 550 new figures including new anatomy drawings new graphs and algorithms and new photos. Provides diligently updated content throughout based on only the most recent and relevant medical literature. Provides improved organization in sections to enhance navigation and six new chapters: Airway Management for the Pediatric Patient, Procedural Sedation and Analgesia for the Pediatric Patient, Drug Therapy for the Pediatric Patient, Co-Morbid Medical Emergencies During Pregnancy, Drug Therapy in the Geriatric Patient and Global and Humanitarian Emergency Medicine. Expert Consult™ eBook version included with purchase. This enhanced eBook experience allows you to search all of the text figures Q&As and references from the book on a variety of devices. *Tarascon Emergency Department Quick Reference Guide* D. Brady Pregerson, 2010-12-15 Tarascon Emergency Department Quick Reference Guide is a concise and easy to use guide filled with essential resources for physicians nurses and EMTs working in an emergency setting. This pocket sized reference is fully indexed and contains diagrams maps tables and graphs as well as many EKG tracings. The Tarascon Emergency Department Quick Reference Guide features a one page emergency medical dictionary in 17 foreign languages plus sections on physical exam diagnostic tests procedures and sedation diagnoses risk management med legal and billing practical advice and much more. **Clinical Nursing Skills and Techniques - E-Book** Anne G. Perry, Patricia A. Potter, Wendy R. Ostendorf, 2017-01-16 NEW Clinical Debriefs are case based review questions at the end of each chapter that focus on issues such as managing conflict care prioritization patient safety and decision making. NEW Streamlined theory content in each chapter features a quick easy to read bullet format to help reduce repetition and emphasize the clinical focus of the book. NEW Sample documentation for every skill often includes notes by exception in the SBAR format. NEW SI units and using generic drug names are used throughout the text to ensure content is appropriate for

Canadian nurses as well *Data Integrity in Pharmaceutical and Medical Devices Regulation Operations* Orlando Lopez, 2016-11-03 Data integrity is fundamental in a pharmaceutical and medical devices quality system This book provides practical information to enable compliance with data integrity while highlighting and efficiently integrating worldwide regulation into the subject The ideas presented in this book are based on many years experience in regulated industries in various computer systems development maintenance and quality functions In addition to case studies a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved **Fundamentals of Nursing - E-Book** Patricia A. Potter, Anne Griffin Perry, Patricia Stockert, Amy Hall, 2016-02-02 It s your complete guide to nursing from basic concepts to essential skills Fundamentals of Nursing 9th Edition prepares you to succeed as a nurse by providing a solid foundation in critical thinking evidence based practice nursing theory and safe clinical care in all settings With illustrated step by step guidelines this book makes it easy to learn important skills and procedures Care plans are presented within a nursing process framework and case studies show how to apply concepts to nursing practice From an expert author team led by Patricia Potter and Anne Griffin Perry this bestselling nursing textbook helps you develop the understanding and clinical reasoning you need to provide excellent patient care 51 skills demonstrations provide illustrated step by step instructions for safe nursing care and include rationales for each step 29 procedural guidelines provide streamlined step by step instructions for performing basic skills UNIQUE Critical Thinking Models in each clinical chapter show how to apply the nursing process and critical thinking to achieve successful clinical outcomes Evidence Based Practice chapter shows how nursing research helps in determining best practices UNIQUE Caring for the Cancer Survivor chapter prepares nurses to care for cancer patients who may still face physical and emotional issues Case studies include unique clinical application questions and exercises allowing you to practice using care plans and concept maps The 5 step nursing process provides a consistent framework for care and is demonstrated in more than 20 care plans 15 review questions in every chapter test your retention of key concepts with answers available in the book and on the Evolve companion website Practical study tools on Evolve include video clips of skills skills checklists printable key points a fluid electrolytes tutorial a concept map creator an audio glossary and more UNIQUE Clear streamlined writing style makes complex material more approachable More than 20 concept maps show care planning for clients with multiple nursing diagnoses Key points and key terms in each chapter summarize important content for more efficient review and study Unexpected Outcomes and Related Interventions for each skill alert you to potential problems and appropriate nursing actions Delegation coverage clarifies which tasks can and cannot be delegated A glossary provides quick access to definitions for all key terms **Pain Medicine** Salim M. Hayek, Binit J. Shah, Mehul J. Desai, Thomas C. Chelmsky, 2015-04-16 Pain Medicine approaches the management of common chronic pain conditions using a unique interdisciplinary approach focusing on multiple facets of patients clinical presentations The comprehensive discussions in each chapter are centered on a

vignette that mimics a fairly typical case presentation In addition to detailed classical descriptions of the epidemiology pathophysiology prognosis and confounding psychosocial factors of each disease entity the text provides various interdisciplinary management approaches The case based approach illustrates key clinical points and demonstrates how practitioners from a variety of disciplines can work together to deliver optimal patient care The ACGME criteria for fellowship training in Pain Medicine calls for an interdisciplinary approach with required training and exposure to the fields of Anesthesiology Neurology Psychiatry and Physical Medicine Rehabilitation As this trend is occurring in private pain clinics and practices as well as in academic institutions there is a need for a volume which integrates the approaches of the various disciplines into a coherent whole to guide clinicians and trainees in the interdisciplinary management of pain With each chapter authored by respected experts in the key specialties involved with pain management Pain Medicine is a highly applicable clinical reference for practitioners an excellent anchor text for fellows and residents in training and a thorough review for initial board certification as well as maintenance of certification exams

Clinical Gastrointestinal Endoscopy E-Book Vinay Chandrasekhara,B. Joseph Elmunzer,Mouen Khashab,V. Raman Muthusamy,2018-01-17 Now thoroughly up to date Clinical Gastrointestinal Endoscopy 3rd Edition by Drs Vinay Chandrasekhara Mouen Khashab B Joseph Elmunzer and V Raman Muthusamy ensures that you stay current with the latest technology and techniques in GI endoscopy An all new editorial team newly updated images and a reorganized format make this reference an easy to use source of reliable information on a full range of topics including anatomy pathophysiology and therapeutic management options in addition to the latest GI procedures and technologies Offers state of the art coverage of bariatric surgery therapeutic EUS device assisted enteroscopy image guided therapy intramural endotherapy and much more Features 100 updated videos with author voiceovers as well as 1 000 revised photographs endoscopic images and anatomical drawings Provides a fresh perspective and expert guidance from an entirely new editorial team Includes many more references per chapter as well as further references online Presents material in a newly restructured organ based format for quick reference Expert Consult™ eBook version included with purchase This enhanced eBook experience allows you to search all of the text figures and references from the book on a variety of devices

Firestein & Kelley's Textbook of Rheumatology - E-Book Gary S. Firestein,Ralph C. Budd,Sherine E Gabriel,Iain B. McInnes,James R. O'Dell,2020-07-05 Through 10 outstanding editions Kelley Firestein s Textbook of Rheumatology has provided authoritative in depth guidance in rheumatology with an ideal balance of basic science and clinical application The 11th Edition of this classic text continues this tradition of excellence while keeping you abreast of recent advances in genetics and the microbiome new therapies such as biologics and biosimilars and other rapid changes in the field It provides comprehensive global coverage of all aspects of diagnosis screening and treatment in both adults and children in a user friendly full color reference Covers everything from basic science immunology anatomy and physiology to diagnostic tests procedures and specific disease processes including key data on therapeutic

outcomes to better inform clinical decision making Includes new chapters on Innate Lymphoid Cells and Natural Killer Cells Pathogenesis of Inflammasome Mediated Diseases Bisphosphonates Ultrasound Evaluation of the Musculoskeletal System and Evaluation of Monoarticular and Polyarticular Arthritis Features 1 200 high quality illustrations including superb line art quick reference tables and full color clinical photographs Shares the knowledge and expertise of internationally renowned scientists and clinicians including new editor Dr Gary Koretzky specialist in immunology and rheumatology Demonstrates the complete musculoskeletal exam in online videos including abnormal findings and the arthroscopic presentation of diseased joints Enhanced eBook version included with purchase Your enhanced eBook allows you to access all of the text figures and references from the book on a variety of devices Medical Decision-Making on Behalf of Young Children Imogen Goold, Cressida Auckland, Jonathan Herring, 2020-09-17 In the wake of the Charlie Gard and Alfie Evans cases a wide ranging international conversation was started regarding alternative thresholds for intervention and the different balances that can be made in weighing up the rights and interests of the child the parent s rights and responsibilities and the role of medical professionals and the courts This collection provides a comparative perspective on these issues by bringing together analysis from a range of jurisdictions across Europe North and South America Africa and Asia Contextualising the differences and similarities and drawing out the cultural and social values that inform the approach in different countries this volume is highly valuable to scholars across jurisdictions not only to inform their own local debate on how best to navigate such cases but also to foster inter jurisdictional debate on the issues The book brings together commentators from the fields of law medical ethics and clinical medicine across the world actively drawing on the view from the clinic as well as philosophical legal and sociological perspectives on the crucial question of who should decide about the fate of a child suffering from a serious illness In doing so the collection offers comprehensive treatment of the key questions around whether the current best interests approach is still appropriate and if not what the alternatives are It engages head on with the concerns seen in both the academic and popular literature that there is a need to reconsider the orthodoxy in this area Braunwald's Heart Disease - E-Book Peter Libby, 2021-10-15 Current comprehensive and evidence based Braunwald s Heart Disease remains the most trusted reference in the field and the leading source of reliable cardiology information for practitioners and trainees worldwide The fully updated 12th Edition continues the tradition of excellence with dependable state of the art coverage of new drugs new guidelines more powerful imaging modalities and recent developments in precision medicine that continue to change and advance the practice of cardiovascular medicine Written and edited by global experts in the field this award winning text is an unparalleled multimedia reference for every aspect of this complex and fast changing area Offers balanced dependable content on rapidly changing clinical science clinical and translational research and evidence based medicine Includes 76 new contributing authors and 14 new chapters that cover Artificial intelligence in Cardiovascular Medicine Wearables Influenza Pandemics COVID 19 and Cardiovascular Disease Tobacco and Nicotine Products in Cardiovascular

Disease Cardiac Amyloidosis Impact of the Environment on Cardiovascular Health and more Features a new introductory chapter Cardiovascular Disease Past Present and Future by Eugene Braunwald MD offering his unique visionary approach to the field of cardiology Dr Braunwald also curates the extensive bimonthly online updates that include Hot Off the Press with links to Practice Update and Late Breaking Clinical Trials Provides cutting edge coverage of key topics such as proteomics and metabolomics TAVR diabetocardiology and cardio oncology Contains 1 850 high quality illustrations radiographic images algorithms and charts and provides access to 215 videos called out with icons in the print version Highlights the latest AHA ACC and ESC guidelines to clearly summarize diagnostic criteria and clinical implications Provides tightly edited focused content for quick dependable reference Flexible format options include either one or two volumes in print as well as a searchable eBook with ongoing updates Enhanced eBook version included with purchase Your enhanced eBook allows you to access all of the text figures and references from the book on a variety of devices **Foundations for Population Health**

in Community/Public Health Nursing - E-Book Marcia Stanhope, Jeanette Lancaster, 2017-09-20 Get the essential information you need to know about population health and community health nursing Foundations for Population Health in Community Public Health Nursing 5th Edition includes concise focused coverage of community health nursing from nursing roles and care settings to vulnerable population groups The book uses a practical community oriented approach and places an emphasis on health promotion and disease prevention Practical application of concepts is highlighted throughout the text in case studies critical thinking activities QSEN competencies and Healthy People 2020 objectives QSEN boxes illustrate how quality and safety goals competencies objectives knowledge skills and attitudes can be applied in nursing practice in the community Healthy People 2020 objectives in every chapter address the health priorities and emerging health issues expected in the next decade Genomics coverage provides a history of genetics and genomics and how they impact public community health nursing care Focus on health promotion throughout the text emphasizes initiatives strategies and interventions that promote the health of the community Clinical Application scenarios present practice situations with questions and answers to help you apply chapter concepts to practice in the community Evidence Based Practice boxes highlight current research findings their application to practice and how community public health nurses can apply the study results Levels of Prevention boxes identify specific nursing interventions at the primary secondary and tertiary levels to reinforce the concept of prevention as it pertains to community and public health care Feature box on Linking Content to Practice highlights how chapter content is applied in the role of public community health nursing NEW Coverage of health care reform includes discussions of the impact of The Patient Protection and Affordable Care Act of 2010 ACA on public health nursing and the potential implications of its repeal NEW Check Your Practice boxes feature scenarios and discussion questions to promote active learning **Foundations of Maternal-Newborn and Women's Health Nursing - E-Book** Sharon Smith Murray, Emily Slone McKinney, 2013-10-01 With easy to read coverage of nursing care for women and

newborns Foundations of Maternal Newborn Women's Health Nursing 6th Edition shows how to provide safe competent care in the clinical setting Evidence based guidelines and step by step instructions for assessments and interventions help you quickly master key skills and techniques Also emphasized is the importance of understanding family communication culture client teaching and clinical decision making Written by specialists in maternity nursing Sharon Smith Murray and Emily Slone McKinney this text reflects the latest QSEN competencies and the accompanying Evolve website includes review questions to prepare you for the NCLEX exam Nursing Care Plans help you apply the nursing process to clinical situations Procedure boxes provide clear instructions for performing common maternity skills with rationales for each step UNIQUE Therapeutic Communications boxes present realistic nurse patient dialogues identifying communication techniques and showing to respond when encountering communication blocks Communication Cues offer tips for interpreting patients and families verbal and nonverbal communication Critical Thinking exercises focus on clinical situations designed to test your skills in prioritizing and critical thinking Updated drug guides list important indications adverse reactions and nursing considerations for the most commonly used medications Check Your Reading helps you assess your mastery of key content Critical to Remember boxes highlight and summarize need to know information Want to Know boxes provide guidelines for successful client education Glossary provides definitions of all key terms NEW Safety Alerts help you develop competencies related to QSEN and safe nursing practice NEW Unfolding case studies help you apply what you've learned to practice UPDATED Evidence Based Practice boxes highlight the latest research and the most current QSEN Quality and Safety Education for Nurses practice guidelines for quality care UPDATED content includes the late preterm infant fetal heart rate pattern identification obesity in the pregnant woman and the QSEN competencies Public Health Nursing - E-Book Marcia Stanhope, Jeanette Lancaster, 2014-07-21 Now in its 8th edition the gold standard in community health nursing provides comprehensive and up to date content to keep you at the forefront of the ever changing community health climate and prepare you for an effective nursing career In addition to a solid foundation in concepts and interventions for individuals families and communities you will find real life applications of the public nurse's role Healthy People 2020 initiatives new chapters on forensics and genomics plus timely coverage of disaster management and important client populations such as pregnant teens the homeless immigrants and more Evidence Based Practice boxes illustrate how the latest research findings apply to public community health nursing Separate chapters on disease outbreak investigation and disaster management describe the nurse's role in surveilling public health and managing these types of threats to public health Separate unit on the public community health nurse's role describes the different roles and functions of the public community health nurse within the community Levels of Prevention boxes show how community public health nurses deliver health care interventions at the primary secondary and tertiary levels of prevention What Do You Think Did You Know and How To boxes use practical examples and critical thinking exercises to illustrate chapter content The Cutting Edge highlights significant issues and new

approaches to community oriented nursing practice Practice Application provides case studies with critical thinking questions Separate chapters on community health initiatives thoroughly describe different approaches to promoting health among populations Appendixes offer additional resources and key information such as screening and assessment tools and clinical practice guidelines Linking Content to Practice boxes provide real life applications for chapter content NEW Healthy People 2020 feature boxes highlight the goals and objectives for promoting health and wellness over the next decade NEW The Nurse in Forensics chapter focuses on the unique role of forensic nurses in public health and safety interpersonal violence mass violence and disasters NEW Genomics in Public Health Nursing chapter includes a history of genetics and genomics and their impact on public community health nursing care

Fundamentals of Medical-Surgical Nursing
Anne-Marie Brady, Catherine McCabe, Margaret McCann, 2014-01-28 Fundamentals of Medical Surgical Nursing
Fundamentals of Medical Surgical Nursing A Systems Approach Fundamentals of Medical Surgical Nursing is a comprehensive yet easy to read overview of medical and surgical nursing designed specifically to support all nursing students learning to care for the adult patient Highly illustrated and with an easy to follow systems based structure it provides a thorough foundation in anatomy and physiology pathophysiology medical management and nursing care for the full spectrum of adult health conditions KEY FEATURES Extensive coverage of principles of nursing assessment medication administration infection prevention and control and nutritional care Key need to know information and definitions for the anatomy physiology and pathology of a range of illnesses and conditions Detailed overviews of nursing care including patient education treatment and complications An online resource centre with a range of extras for both lecturers and students including case studies reflective activities interactive multiple choice questions and further reading lists Fundamentals of Medical Surgical Nursing is the ideal textbook to help students succeed on their adult nursing course with online self test www.wileyfundamentalseries.com/medicalnursing Interactive multiple choice questions Reflective questions for downloading Case studies Links to online resources When you purchase the book you also receive access to the Wiley E Text Powered by VitalSource This is an interactive digital version of the book featuring downloadable text and images highlighting and notetaking facilities bookmarking cross referencing in text searching and linking to references and abbreviations Fundamentals of Medical Surgical Nursing is also available on CourseSmart offering extra functionality as well as an immediate way to access the book For more details see www.coursesmart.co.uk 9780470658239 **Good Clinical Practice**, 2003

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