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(Rebecca Bechtelar)

THE MICHIGAN CIRCUIT COURT REPORTER EMBRACING DECISIONS OF THE COURTS AND ARTICLES UPON QUESTIONS OF PRACTICE IN THE CIRCUIT COURTS OF THE STATE OF M



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RareBooksClub. Paperback. Book Condition: New. This item is printed on demand. Paperback. 118 pages. LC Number: KF27 . S39956 2009f OCLC Number: (OCoLC)557601871 Subject: Biologicals -- Effectiveness -- Measurement -- Standards -- United States. Excerpt: . . . 11 their medicines and accurately identify which parts of the protein are most impor-tant, in order to ensure optimal product safety and efficacy. One safety concern with biotechnology medicines - immunogenicity - occurs when the body does not recognize the protein being administered, triggering the immune system to produce antibodies, which are special proteins that bind to the offending protein in an attempt to neutralize it and clear it from the body. Depending on the nature of the protein administered, immunogenicity can cause the medicine to be ineffectual, or could result in adverse reactions ranging from mild to life-threat-ening. Because of the potential for immunogenicity, it is essential for patient safety that scientists and clinicians are able to properly, accurately, and consistently meas-ure antibodies that develop in patients against biotechnology medicines. It has been shown that subtle or even undetectable changes in the structural properties of a biotechnology medicine can have an impact on its safety, efficacy or immunogenicity. Therefore, the laboratory-based analytical methods used to under-stand the structural characteristics of biological medicines play a critical role in the product development process. The earlier on in development a company can develop sound and rigorous meas-urement methods, the earlier it can alter the product or the process as necessary to maximize the chance of success with a new biologic - ideally, before expensive clinical studies are started and patients given a medicine that may not work as expected. Having standard methods and reference materials available as soon as prod-uct development begins should give companies a head start in creating a successful product. Furthermore,...



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