

Rancangan Prototipe Otomasi dan Integrasi Sistem Informasi Penilaian Maturitas Industri Farmasi untuk Penjaminan Mutu dan Keamanan Obat di Badan Pengawas Obat dan Makanan

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Abstrak

<div style="text-align: justify;">Sebagai Upaya mendorong pelaku usaha untuk meningkatkan kepatuhan terhadap regulasi dan standar dalam rangka menjamin keamanan, mutu dan khasiat obat serta peningkatan daya saing industri farmasi, Badan POM memiliki program penilaian maturitas industri farmasi. Namun, proses penilaian masih dilakukan secara manual sehingga kurang efisien dan berpotensi menimbulkan kesalahan. Penelitian ini bertujuan mengembangkan prototipe otomasi dan integrasi Sistem Informasi Penilaian Maturitas Industri Farmasi dengan System Development Life Cycle (SDLC) menggunakan metode prototipe. Analisis kebutuhan dilakukan menggunakan kerangka PIECES, sedangkan pengujian sistem menggunakan blackbox testing meliputi System Integration Test (SIT) dan User Acceptance Test (UAT) dengan lingkup uji simulasi persepsi terhadap pengguna dan perhitungan skor. Hasil penelitian menunjukkan bahwa sistem berhasil mengotomasi proses penilaian maturitas, terintegrasi dengan e-Sertifikasi CPOB dan Sistem Informasi Pengawasan Terpadu (SIPT), serta otomasi skor dan level maturitas. Sistem meningkatkan efisiensi, akurasi, dan ketertelusuran data, serta mendukung transformasi digital BPOM untuk efektivitas pengawasan produksi obat berbasis data dan risiko.</div><hr /><div style="text-align: justify;">The Indonesian Food and Drug Authority (BPOM) has established the Pharmaceutical Industry Maturity Assessment Program to encourage pharmaceutical industry to comply with regulatory requirements and quality standards, thereby ensuring the safety, quality, and efficacy of drugs, as well as strengthening the competitiveness of the pharmaceutical industry. However, the maturity assessment process is currently conducted manually, resulting in inefficiencies, fragmented data management, and an increased risk of calculation errors. This study aimed to develop a prototype of an automated and integrated Pharmaceutical Industry Maturity Assessment Information System using the System Development Life Cycle (SDLC) with a Prototype development approach. System requirements were identified using the PIECES framework, while system performance was evaluated through black-box testing, including System Integration Testing (SIT) and User Acceptance Testing (UAT), as well as simulation-based validation of user and maturity score calculations. The developed system successfully automated the end-to-end maturity assessment process, integrated data from e-certification and SIPT, and automated maturity score calculation and level maturity determination. The prototype demonstrated improved operational efficiency, calculation accuracy, and data traceability while providing real time information to support evidence based and risk-based inspection. These findings indicate that the proposed system has the potential to strengthen BPOM's digital transformation in pharmaceutical manufacturing oversight.</div>