



## Quality Assurance: Results from the Use of PDAs in Regulatory Efforts

O. Kowero,<sup>1</sup> L. Mshana,<sup>1</sup> Z. Msuya,<sup>1</sup> M. Ndomondo-Sigonda,<sup>1</sup>  
B. Kozaras,<sup>2</sup> H. Kraushaar,<sup>3</sup> T. Layloff,<sup>3</sup> G. Phumtim,<sup>3</sup> P. Risha,<sup>3</sup> and A. Speed<sup>3</sup>

<sup>1</sup> Tanzania Food and Drugs Authority, Tanzania

<sup>2</sup>SATELLIFE, USA

<sup>3</sup>Management Sciences for Health, USA

In March 2003, Management Sciences for Health, working closely with the Tanzania Food and Drugs Authority (TFDA), implemented a data collection system for the recently strengthened activities in the port of entry (POE) and postmarketing surveillance (PMS) inspection programs that made use of personal digital assistants (PDAs). Field inspectors, who require ready access to the TFDA's drug marketing authorization database and needed a method for efficiently collecting and submitting inspection data, were trained on the use of the devices and forms and given a PDA to use in their daily efforts. The units were deployed to inspectors responsible for monitoring the POE and PMS programs in the northern part of Tanzania. After some initial piloting with an alpha software version, a beta version was developed that the inspectors have used in their everyday duties since October 2004. Follow-up surveys with the inspectors after six months of continuous use revealed a number of points about the program.

Positive points about the program include the following: It reduced the inspectors' workload by eliminating the need for the inspectors to carry and maintain current paper copies of their numerous inspection forms, to file completed inspection forms in an orderly and accessible fashion, and to prepare weekly summaries of observations. In addition, the PDA implementation has helped to increase accuracy of data entry; provided a mechanism for getting more timely and definitive information about new approvals; and helped structure, order, and discipline the inspection process, resulting in improved consistency. Furthermore, the use of PDAs has contributed to the inspectors' prestige and recognition, improving their confidence in their work.

Negative points raised by the inspectors include the fact that the software program is too structured to deal with exceptions that fall outside of the survey questions. In addition, delays in obtaining monthly updates of the drug marketing authorization databases have hindered their work; however, the delays were not related to the PDAs per se but to underlying administrative processes, in that the TFDA does not keep the central databases current due to a lack of IT/MIS infrastructure support and resources.

Overall, inspectors and TFDA management involved with the PDA program have found the use of PDAs to be a positive addition to the organization as a whole. However, some questions still remain regarding the sustainability of the project given the drug marketing authorization database maintenance problem mentioned above and TFDA IT resource priorities in resolving that issue.

Lessons learned during the program include: Adequate IT support and buy-in from management is necessary for ultimate success of the project, parallel systems are required for the pilot testing phase and beyond until the software and associated processes and



---

procedures are fully stabilized, sound infrastructure and administrative processes need to be in place and functioning before a PDA program is implemented, and a combination of lecture-style and hands-on training must be employed at the beginning and at intervals thereafter to ensure full understanding of the tool.