MPL LABORATORIES

FDA/DEA REGISTERED
NJDEP CERTIFIED
ISO/IEC 17025:2005 ACCREDITED

EMSL ANALYTICAL, INC. DBA
MPL LABORATORIES
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December 19, 2016

Management of Change: Customer Notification - Discontinuation of ISO 9001:2008 Certification

MPL Laboratories is currently certified to ISO 9001:2008 through a third party certification provider. Our current certificate expires on December 23, 2016. MPL does not intend to undergo the re-certification audit that is required to renew this certificate.

MPL has three reasons for this decision:

1. MPL is accredited to ISO/IEC 17025:2005 quality guidelines by Perry Johnson Laboratory Accreditation, Inc. The 17025:2005 International Standard is very similar to the 9001:2008 International Standard. The following are excerpts from the Introduction section of the 17025:2005 International Standard:

> "Accreditation bodies that recognize the competence of testing and calibration laboratories should use this International Standard as the basis for their accreditation."
>
> "Growth in the use of management systems generally has increased the need to ensure that laboratories which form part of larger organizations or offer other services can operate to a quality management system that is seen as compliant with ISO 9001 as well as with this International Standard."
>
> "Care has been taken, therefore, to incorporate all those requirements of ISO 9001 that are relevant to the scope of testing and calibration services that are covered by the laboratory's management system."
>
> "Testing and calibration laboratories that comply with this International Standard will therefore also operate in accordance with ISO 9001."

2. Health Canada and other regulatory agencies do not accept ISO 9001:2008 as an adequate basis for a laboratory's quality management system. Health Canada only accepts ISO/IEC 17025:2005 due to its focus upon laboratory competency. Many of our customers conduct business internationally. These customers are not permitted to send microbiological samples to a laboratory that lacks ISO/IEC 17025:2005 accreditation.

3. Transition to the new version, ISO 9001:2015, is due in September of 2018. It is significantly different. It focuses on business management rather than quality management. As such, it will no longer coincide with the quality management system that MPL has developed to comply with ISO/IEC 17025:2005 and ISO 9001:2008.

It is also important to note that MPL remains FDA registered, successfully completing its most recent FDA inspection in September of 2016 with no observations or findings. If you have any questions or concerns regarding this change, please feel free to contact me directly to discuss them in more detail.

Simeon Griffin, Quality Assurance Director

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Certificate US10/81788

The management system of

Marypaul Laboratories, Inc.

12 Wilson Drive,
Sparta, NJ 07871, United States

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities:

A Microbiology Testing Laboratory serving the Pharmaceutical, Medical Device, Cosmetic, Personal Care, and Food Industries. Excluding 7.3 & 7.5.2

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization.

This certificate is valid from 23 December 2013 until 23 December 2016 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 2 : 20 December 2013.
Certified since December 2010.

Authorized by

Zachary C. Pivarnik
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This certificate remains the property of SGS and shall be returned upon request