

ESTP COMMITTEE OF REGULATORY AND SCIENTIFIC STANDARDS (CRSS) – MAY 2024

MISSION AND GUIDANCE DOCUMENT

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General

The CRSS is a dedicated committee under the auspices of the European Society of Toxicologic Pathology (ESTP). Team members are not chosen but volunteer to participate in the Committee and are all members of the ESTP. The number of members of the CRSS may vary but should be composed of at least 5 members. The respective ESTP STP SRPC liaison is automatically a member of the CRSS and should regularly participate in the meetings. The CRSS chair is responsible to ensure that regular meetings are held, communication to the ESTP board, recruitment of appropriate members to the CRSS, its continuation and the fulfilment of its tasks. The ESTP administrative support is responsible for the establishment of the meeting minutes and supports the CRSS in communication with other societies.

CRSS members commit to a regular participation in the meetings (generally 5-9 per year) of a minimum of 6 meetings annually to ensure a quorum for decision making and appropriate cover of all necessary activities.

Mission

The overall mission of the ESTP Regulatory and Scientific Standards Committee is

1. *to keep the ESTP membership updated on guideline documents and regulatory activities impacting the field of toxicologic pathology & drug/agrochemical development;*
2. *to promote scientific excellence and appropriate visibility of ESTP member/working group contributions via reviewing/supporting publications for the Journal of Toxicologic Pathology in collaboration with the ESTP EC, and*
3. *to appropriately influence regulatory guidance in the wider field of toxicologic pathology via commenting Draft guidelines in collaboration with the ESTP membership.*

This includes (but is not necessarily limited to):

- Review & Response to Draft regulatory guidelines (FDA, OECD, ICH, EMEA, EPA) impacting the work of toxicologic pathologists.
- Information about Final Regulatory guidelines (or updates) to the ESTP membership (via e-mail and/or LinkedIn)
- Review of Publications provided by STP/BSTP/ESTP for publication in Toxicologic Pathology in the scope of the respective MoU and ESTP Procedures.
- Support ESTP working groups/authors in providing guidance on the Categories of Publication and review of the respective Charters.

- May initiate new proposals for Working Groups to prepare Best Practice Papers, Points to Consider Papers or Opinion Papers which are interesting for the toxicologic pathology community.
- Link to STP SRPC (Scientific Regulatory Policy Committee) via the ESTP STP SRPC liaison.
- Link to ESTP Associate Editor regarding ESTP banner publications in the Journal of Toxicologic Pathology
- Create efficient and robust process documents and participate in review and finalization of process documents and Society MoUs which impact the above-mentioned activities of the CRSS.

Procedure:

- Internal communication within the CRSS is guaranteed by regular on-line meetings in which all main activities of the committee mentioned above are discussed. Communication also occurs via e-mail when more information, detail or contribution for specific subjects or issues is needed.
- Meetings minutes are prepared and made available in the member area of the ESTP website.
- External communication is mainly done by e-mail, in most cases via the ESTP administrator.
- Individual members of the CRSS are responsible to regularly review websites of specific regulatory bodies (i.e. EMA, FDA, ICH, OECD, EPA, EFSA/ECA) to inform the Committee of any new draft guidelines or updates which fall within the scope of the CRSS.
- The ESTP STP SRPC liaison will share STP SRPC activities at the CRSS meetings and regularly share STP SRPC minutes with the CRSS and the ESTP EC.
- The CRSS reviews Draft publications to be published under the ESTP banner in Toxicologic Pathology and equally Draft publications to be reviewed from other societies seeking ESTP endorsement/approval/ratification, as well as in the scope of the societies MoUs following the respective procedures.
- Review & Response to Draft Guidelines
 - For **Guidelines impacting directly the work of Toxicologic Pathologists**, depending on the Review period for comments, the CRSS first reaches out to the ESTP membership to collect comments, and then prepares a collation of comments with a general assessment (if applicable) to be shared with the ESTP EC for comment and endorsement within a given timeframe; the ESTP EC will respond within the timeframe following the respective procedure (generally within 10 WDs).
 - The CRSS chair (or delegate) is responsible to organize a timely submission of the comments document in collaboration with the ESTP EC and administrator (official signatures)
- Information about Final or updated Regulatory Guidelines:
 - **Final/Updated Regulatory Guidelines:** An informative email with bullet points highlighting the relevant information is prepared by a member and is after approval by other members (at least one) distributed to the ESTP-members via the ESTP

administrator for information. Depending on the impact for the field of Toxicologic Pathology, the information is shared with the Councillor for the Website to be posted in the Members Only area.

- Review of Draft Projects/Publications under ESTP banner for Publication in the Journal of Toxicologic Pathology
 - **Working group projects:** when solicited, the CRSS provides the Draft Charter form to gather the relevant overview to be able to provide guidance on the potential category of the final publication
 - **Draft Publication for final endorsement:** the CRSS reviews the publication and provides the document (incl. comments; if applicable) with a recommendation to the ESTP EC for approval following the respective procedure and timelines.
- Review of Draft Projects/Publications from STP/BSTP or other societies for Publication in the Journal of Toxicologic Pathology
 - the CRSS reviews the publication and provides the document (incl. comments; if applicable) with a recommendation to the ESTP EC for approval following the respective procedure and timelines.
- General support
 - Active involvement in preparing or updating SOPs or Society MoUs (e.g. on the different publication categories).
 - Propose new subjects for Working Groups that can prepare publications on interesting issues for the Toxicologic Pathology Community.

Documents which impact the Work of the ESTP CRSS committee:

- ESTP Procedure for Review of Manuscripts & Submission to Tox Path Journal; Standard Operating Procedure (November 2023; Version 4)
- STP/ESTP/BSTP Memorandum of Understanding (MoU) regarding the publication of manuscripts in Toxicologic Pathology - version 2024