Consult MDSAP QMS P0009 Corrective Action (CA) Procedure and MDSAP QMS P0010 Preventive Action (PA) Procedure for additional information on handling complaints and or customer feedback, as well as initiating related corrective and/or preventive action(s).

1. When a complaint or other type of feedback is received or identified by MDSAP team, including Regulatory Authority Council (RAC) and participating Regulatory Authorities (RA's):
    a. For complaints and other concerns, the receiver completes the top portion of the "Complaints and/or Customer Feedback" Form, stopping at "Corrective Action/Preventive Action" and proceeds to steps 2-6 below.
    b. For other types of feedback, the receiver documents the information on the "Complaints and/or Customer Feedback" Form and submits it to the RAC Secretariat.
    c. Complaints and other customer feedback with anonymous and confidential sources should still be documented. However, any possible identifying information should not be recorded.

2. The receiver – CA assignee should discuss the submission with the site management and/or team leader and if needed with Regulatory Authority Corrective Action (RA/CA) Contact to discuss causes and follow-up.

3. A corrective or preventive action is documented on form MDSAP QMS F0009.1 Corrective Action and Problem Report (CAPR) Form. (It is suggested to search the CA/PA database or request the information from the CA/PA Administrator for the possibility of applying known corrections that have been previously determined from past corrective actions.)

4. Both completed forms are submitted to MDSAP Site Management and CA/PA System Manager and approval before the CA assignee finalizes the process.

5. Upon receipt of the form (s), the MDSAP Site Management and CA/PA System Manager will assess to determine impact on operations and quality. If further investigation is needed, the CA assignee and MDSAP Site Management will determine causes and recommend actions on a new or existing CAPR, which will be submitted to MDSAP Review Board and RAC Chair.