Third Party Authorization Sample Template

Authorization for a Third Party To File a Regulatory Activity on Behalf of the Manufacturer/Sponsor[1]

I, _____ authorize _____
(third party individual)

of _____ to file a regulatory activity
(*third party company name*)

for _____ on behalf of
(*name of product*)

_____
(Drug Manufacturer / Sponsor Name)

Signed: _____.

Print name: _____.

Title: _____.

Manufacturer/Sponsor: _____.

Date: _____.

1. A Third Party Authorization letter is required within the initial transaction of a regulatory transaction when the:
    - Regulatory contact for the transaction, indicated on the RT file, is a third party acting on behalf of the manufacturer/sponsor; **and**
    - Regulatory activity type is one of the following (including administrative submissions): COV19, COV19A, NDS, SNDS, ANDS, SANDS, SNDS-C, SANDS-C, NC, EUNDS, EUSNDS, EUANDS, EUSANDS, DINA, DINB, DIND, DINF, PDC, PDC-B.

    The authorization letter is only required once per regulatory activity unless the third party has changed, in which case a new authorization letter will be required. The authorization letter should be provided as a separate PDF document.