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|---------------------------------------------------------------------------------------------------------------|------------------------------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>(51) International Patent Classification:</b>                                                              |                              |         | <b>(72) Inventor: TULSYAN, Aditya;</b> c/o AMGEN INC., One Amgen Center Drive, Mail Stop 28-5-A, Thousand Oaks, California 91320-1799 (US).                                                                                                                                                                                                                                                                                                                                                                       |
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| <b>(21) International Application Number:</b>                                                                 |                              |         | <b>(74) Agent: BATEMAN, Andrew W.;</b> Marshall, Gerstein & Borun LLP, 233 S. Wacker Drive, 6300 Willis Tower, Chicago, Illinois 60606-6357 (US).                                                                                                                                                                                                                                                                                                                                                                 |
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**(54) Title:** AUTOMATIC CALIBRATION AND AUTOMATIC MAINTENANCE OF RAMAN SPECTROSCOPIC MODELS FOR REAL-TIME PREDICTIONS

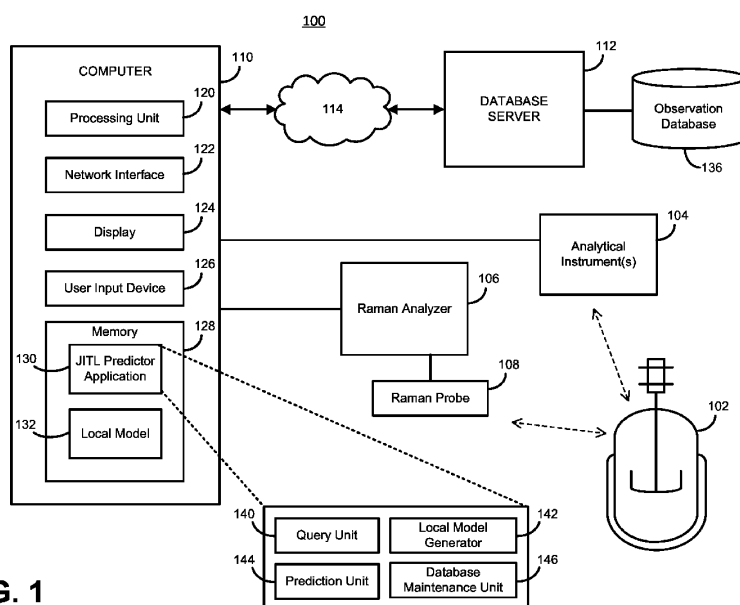


FIG. 1

**(S7) Abstract:** A method for monitoring and/or controlling a biopharmaceutical process includes determining a query point associated with scanning of the process by a spectroscopy system (e.g., a Raman spectroscopy system), and querying an observation database containing observation data sets associated with past observations of biopharmaceutical processes. Each of the observation data sets includes spectral data and a corresponding actual analytical measurement. Querying the observation database includes selecting as training data, from among the observation data sets, those data sets that satisfy one or more relevancy criteria with respect to the query point. The method also includes using the selected training data to calibrate a local model specific to the biopharmaceutical process. The local model (e.g., a Gaussian process model) is trained to predict analytical measurements based on spectral data inputs. The method also includes using the local model to predict an analytical measurement of the biopharmaceutical process.

SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,  
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